Original article

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Risk factors for unfavourable postoperative outcome in patients with Crohn's disease undergoing right hemicolectomy or ileocaecal resection. An international audit by ESCP and S-ECCO

2015 European Society of Coloproctology collaborating group[1]

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Abstract

Aim Patient- and disease-related factors, as well as operation technique, all have the potential to impact on postoperative outcome in Crohn's disease. The available evidence is based on small series and often displays conflicting results. The aim was to investigate the effect of preoperative and intra-operative risk factors on 30-day postoperative outcome in patients undergoing surgery for Crohn's disease.

Method This was an international prospective snapshot audit including consecutive patients undergoing right hemicolectomy or ileocaecal resection. The study analysed a subset of patients who underwent surgery for Crohn's disease. The primary outcome measure was the overall Clavien–Dindo postoperative complication rate. The key secondary outcomes were anastomotic leak, reoperation, surgical site infection and length of stay in hospital. Multivariable binary logistic regression analyses were used to produce odds ratios and 95% confidence intervals.

Results In all, 375 resections in 375 patients were included. The median age was 37 and 57.1% were women. In multivariate analyses, postoperative complications were associated with preoperative parenteral nutrition (OR 2.36, 95% CI 1.10–4.97), urgent/expedited surgical intervention (OR 2.00, 95% CI 1.13–3.55) and unplanned intra-operative adverse events (OR 2.30, 95% CI 1.20–4.45). The postoperative length of stay in hospital was prolonged in patients who received preoperative parenteral nutrition (OR 31, 95% CI 1.08–1.61) and those who had urgent/expedited operations (OR 1.21, 95% CI 1.07–1.37).

Conclusion Preoperative parenteral nutritional support, urgent/expedited operation and unplanned intra-operative adverse events were associated with unfavourable postoperative outcome. Enhanced preoperative optimization and improved planning of operation pathways and timings may improve outcomes for patients.

Keywords Crohn's disease, surgery, resection, postoperative complications, outcome, parenteral nutrition

What does this paper add to the literature?
We describe the first international prospective multicentre study to collect contemporaneous data on this challenging patient cohort. Much of the literature to date consists of small and retrospective series, often from single centres. We identify the common risk factors associated with unfavourable postoperative outcome and make suggestions for potential pathway improvements such as better timing of surgical intervention and preoperative optimization.

Introduction

The postoperative outcome of surgery for Crohn's disease (CD) may be affected by patient, disease, surgical, technical and other perioperative risk factors. Retrospective observational studies have identified several patient-related and disease-related risk factors, including body

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[1]Collaborating members are shown in the Appendix S1, in Supporting information.
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mass index [1], smoking [2], preoperative intra-abdominal abscess or enteric fistula [3], preoperative albumin [4–6], anaemia [7,8], malnutrition [9,10] and preoperative medical treatment [11–13].

Surgeon- and surgery-related risk factors might also be crucial to outcome. The rate of first-time intestinal resection in CD is 29.1% while the 7-year cumulative risk is 28.5% [14]. Surgery in CD patients remains challenging in terms of timing [15], preoperative optimization [8,16,17] and techniques [18]. Many of the suspected risk factors are somewhat controversial, including surgeon's grade of specialization [19], preoperative optimization [8], urgency of surgical intervention [15], use of defunctioning ileostomy [20] and method of access to abdominal cavity [21]. Anastomosis type and configuration have also been debated without robust evidence to support one type or another to date [22,23]. The same applies for the skin closure technique, which has been investigated in obstetrics [24] and orthopaedic [25] surgical wounds but not in CD patients.

The quality of evidence supporting the previously described risk factors is low in the majority of studies due to small sample size and their retrospective nature. There is need for a prospective multicentre study with a large sample size. Our aim was to investigate the effect of patient-, disease- and surgery-related risk factors on the 30-day postoperative outcome in CD patients undergoing right hemicolectomy or ileocaecal resection.

Method

Study design

This was a prospective, multicentre, international snapshot audit of patients undergoing elective or emergency right hemicolectomy or ileocaecal resection over a 2-month period (mid-January to mid-March 2015). Patients were followed up for 30 days after the primary operation. The audit was performed according to a prespecified protocol (http://www.escp.eu.com/research/cohort-studies/2015-audit). The methods used were explained in the recently published primary report from the main study [26]. This study, including only patients undergoing surgery to treat CD, comprises a prespecified subgroup analysis.

Objectives

Our aim was to investigate patient- and surgery-related risk factors that might affect postoperative outcome in CD patients undergoing ileocaecal resection or right hemicolectomy. These factors included age, gender, comorbidity (diabetes and ischaemic heart disease), smoking status, body mass index, statin medication, medical treatment for CD (steroids within 1 week prior to operation, 5-aminosalicylic acid within 1 week prior to operation, immunomodulators within 4 weeks prior to operation, biologics within 12 weeks prior to operation), intra-abdominal abscess/pelvic collection, albumin, serum creatinine, haemoglobin, nutritional support (oral, enteral and parenteral nutrition) and American Society of Anesthesiologists (ASA) grade.

Also, surgeon- and surgery-related factors were collected: urgency of surgery (urgent, i.e. within 24 h; expedited, i.e. within 2 weeks; and elective), previous surgery in the area, details of surgeon in charge (trainee *vs* consultant, colorectal *vs* general surgeon), access to abdominal cavity (open, laparoscopic or laparoscopic converted to open), extent of proximal resection (Fig. 1), details of anastomosis (type, configuration, instruments used), defunctioning/primary stoma, skin closure (suture or stapling), operation duration, and unplanned intra-operative adverse events (UIAEs) including injury to liver, gallbladder, duodenum, kidney, ureter, major blood vessels and bowel injury.

Outcome measures

The primary outcome measure was the overall postoperative complication rate classified according to the Clavien–Dindo scale (Grade I to V). The secondary outcome measures were

1 clinically suspected anastomotic leak defined as either (i) gross anastomotic leakage proved radiologically or clinically or (ii) the presence of an intraperitoneal (abdominal or pelvic) fluid collection on postoperative imaging;
2 surgical site infection within 30 days defined according the Centers for Disease Control criteria;
3 unplanned reoperation within 30 days;
4 length of postoperative stay in hospital (LOS).

Inclusion criteria

Adult patients undergoing right hemicolectomy or ileocaecal resection at a participating hospital during the study period, for CD pathology, via any operative approach and in both the elective and emergency settings, with or without primary anastomosis, performed by colorectal, general or trainee surgeons were included.

Exclusion criteria

Patients undergoing right hemicolectomy or ileocaecal resection as part of a bigger procedure such as subtotal

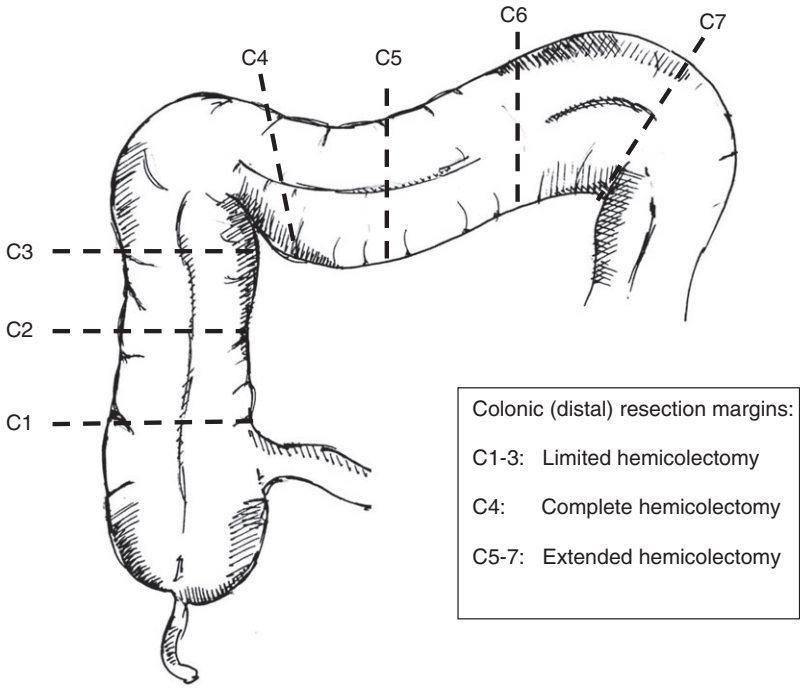


Figure 1 A screen shot of the figure used in the data collection process to map the extent of resection: I, the proximal resection margin; C, the distal resection margin.

colectomy or pan-proctocolectomy, patients in whom the distal colonic transaction point was beyond the splenic flexure and patients undergoing additional upstream strictureplasty or resection to treat concurrent small bowel disease more proximally during the same operation were excluded.

Statistical analysis

Pearson's chi-squared and Fisher's exact tests were applied for categorical variables in univariate analysis, while Mann–Whitney's test was used for continuous variables. Continuous variables are reported by median and interquartile range (IQR). Univariate and multivariate regression models were used to assess the association between risk factors and outcome. For binary outcomes (e.g. complication yes/no), binary logistic regression modelling was used to produce odds ratios. For continuous variables (e.g. LOS), normality was tested and linear regression modelling was used, with results presented as exponential transformations of the regression coefficients. Logarithmic transformation was implemented when needed. Covariates included in regression models were those statistically significant in univariate analyses or those deemed important from clinical experience. Results are presented with corresponding 95% confidence interval. A P value < 0.05 was considered significant. SPSS version 19 was used for descriptive and univariate analyses while R was used for multivariate analyses.

Results

Within the full audit cohort of 3041 patients, 375 operations were performed for CD patients in 151 centres around the world. The operations included in this study represent a subgroup of the main European Society of Coloproctology (ESCP) audit cohort [26].

Preoperative status

Patients' demographics and preoperative data are reported in Table 1. Fourteen patients (3.7%) had an abnormal serum creatinine level preoperatively, and 114 (30.4%) had albumin below normal levels (defined by local laboratories in the participating hospitals). Sixty-eight patients (18.1%) had a preoperative intra-abdominal abscess; however, only 18 (4.8%) had their abscess drained preoperatively with a median interval between abscess drainage and surgery of 29 days (IQR 37). Seventy per cent of patients (263/375) were on one or more types of medical treatment (Table 1). Sixty-six patients (17.8%) received a high steroid dose (defined as 20 mg or more) preoperatively [11].

Table 1 Descriptive details of preoperative medications in 375 CD patients.

Age (median, IQR)	37 years, IQR 23
Gender: female, *n* (%)	214/375 (57.1%)
Comorbidity	
Diabetes mellitus, *n* (%)	7/375 (1.9%)
Ischaemic heart diseases, *n* (%)	10/375 (2.7%)
ASA	
ASA1, *n* (%)	88/375 (23.5%)
ASA2, *n* (%)	239/375 (63.7%)
ASA3, *n* (%)	45/375 (12%)
ASA4, *n* (%)	3/375 (0.8%)
Preoperative albumin below normal limits	117 (31.2%)
Preoperative haemoglobin (median, IQR)	12.8 g/dl, 2.2
Smoking	
Non-smoker, *n* (%)	219/375 (62.2%)
Ex-smoker, *n* (%)	52/375 (14.8%).
Current smoker, *n* (%)	81/375 (21.6%)
Missing	23/375 (6.1%)
Preoperative nutritional support	
Parenteral nutrition	32/375 (8.5%)
Enteral nutrition	12/375/3.2%)
Oral nutrition	28/375 (7.5%)
Body mass index (median, IQR)	22.9, 5.8
Medical treatment	
Cholesterol lowering (statin)	15/375 (4%)
5-ASA agents	73/375 (19.7%)
Mesalazin (Pentasa)	41/375 (11.1%)
Mesalazin	23/375 (6.2%)
Sulfasalazin	9/375 (2.4%)
Steroids	114/375 (30.7%)
Prednisolone	88/375 (23.7%)
Budesonid	15/375 (4%)
Entocort	5/375 (1.3%)
Hydrocortisone	5/375 (1.3%)
Dexamethasone	1/375 (0.3%)
Immunomodulators	127/375 (34.2%)
Azathioprine	97/375 (26.1%)
6-mercuptopurin	6/375 (3.2%)
Methotrexate	10/375 (2.7%)
Purinethol	4/375 (1.1%)
Cyclosporine	2/375 (0.5%)
Biologics	82/375 (22.1%)
Adalimumab	44/375 (11.9%)
Infliximab	33/375 (8.9%)
Vedolizumab	4/375 (1.1%)
Certolizumab	1/375 (0.3%)

IQR, interquartile range; ASA, American Society of Anesthesiologists physical status grading; 5-ASA, 5-aminosalicylic acid.

Intra-operative details

Details of surgical procedures are shown in Table 2. Colorectal specialists, in elective settings, did more than two-thirds of the procedures. The proximal resection margin was 10–30 cm upstream from the ileocaecal valve in the majority of patients and through the caecum or ascending colon distally. A primary anastomosis was performed in 334/375 (89.1%) of the patients; of these 65.9% (220/334) were stapled. Side to side (215/334) stapled anastomoses was the most commonly used configuration usually in the form of extra-corporal anastomosis (105/334). Stomas were constructed in 46/375 (12.3%) of patients.

Postoperative course

In all, 126 patients (33.6%) had one or more postoperative complications, of whom 22 (7.3%) had a complication requiring reoperation within 30 days (Table 3). Median LOS was 7 days (IQR 5). The unplanned readmission rate was 5.3% (20/375).

Univariate analysis

Postoperative complications were associated with parenteral nutrition, comorbidity, urgent/expedited operations and UIAEs (Table 4). The risk of reoperation increased in patients who received parenteral nutrition ($P = 0.14$, OR 3.551, 95% CI 1.216–10.370) and stapled skin closure ($P = 0.023$, OR 2.763, 95% CI 1.115–6.842). Surgical site infection correlated with low preoperative albumin ($P = 0.038$, OR 0.507, 95% CI 0.264–0.973), parenteral nutrition ($P = 0.01$, OR 3.029, 95% CI 1.263–7.267), open access to the abdominal cavity ($P = 0.03$, OR 0.493, 95% CI 0.257–0.943) and stapled skin closure ($P < 0.001$, OR 2.958, 95% CI 1.525–5.737).

Medical treatment was not associated with an increased risk of postoperative complications or reoperation even when this was investigated for each type of the above-mentioned drug categories and different surgical procedures.

Prolonged postoperative LOS (Fig. 2) correlated with parenteral nutrition ($P = 0.002$), ASA grade 3 and 4 ($P < 0.001$), urgent/expedited operations ($P < 0.001$) and stoma construction ($P < 0.001$).

As Fig. 3 shows, peak C-reactive protein level on the third postoperative day correlated with any postoperative complication ($P < 0.01$, OR 66.713, 95% CI 40.397–93.029) and more specifically it correlated with postoperative anastomotic leak ($P = 0.029$, OR 59.807, 95% CI 6.322–113.283).

Multivariate analysis

After adjustment for other preoperative and intra-operative factors, parenteral nutrition, urgent/expedited operations and UIAEs were associated with increased risk of postoperative complications, as reported in Table 4.

Table 2 Details of surgery in 375 CD patients included in the ESCP prospective audit.

Timing of surgery	• Urgent (emergency) within 24 h 54/375 (14.4%) • Expedited within 2 weeks 49/375 (31.1%) • Elective (planned) 272/375 (72.1%)
Previous surgery in the area, *n* (%) 253/375 (67.5%)	• One surgery 32/375 (8.5%) • Two surgeries 57/375 (15.2%) • Three surgeries 33/375 (8.8%)
Surgeon in charge, *n* (%)	• Trainee general surgeon 23/375 (6.1%) • Consultant general surgeon 39/375 (10.4%) • Trainee colorectal surgeon 57/375 (15.2%) • Consultant colorectal surgeon 256/375 (68.3%)
Access to abdominal cavity, *n* (%) Laparoscopy 219/375 (58.4%)	• Laparoscopy 177/375 (47.2%) • Laparoscopy converted to open via midline incision 40/375 (10.7%) • Laparoscopy converted to open via transverse incision 2/375 (0.5%)
Open 156/375 (41.6%)	• Open through midline incision 151/375 (40.3%) • Open through transverse incision 5/375 (1.3%)
Proximal resection margin from caecum (Fig. 1)	• 0 cm from caecum 18/375 (4.8%) • 10 cm from caecum 90/375 (24%) • 20 cm from caecum 104/375 (27.7%) • 30 cm from caecum 63/375 (16.8%) • 40 cm from caecum 81/375 (21.6%) • 50 cm or more from caecum 13/375 (3.5%) • Not stated 6/375 (1.6%)
Distal resection margin (Fig. 1)	• Caecum 138/375 (36.8%) • Mid-colon ascendance 128/375 (34.1%) • Oral for hepatic flexure 26/375 (6.9%) • Anal for hepatic flexure 33/375 (8.8%) • Mid-colon transverse 33/375 (8.8%) • Oral for splenic flexure 6/375 (1.6%) • Splenic flexure 2/375 (0.5%) • Not stated 9/375 (2.4%)
Unplanned intra-operative events, *n* (%): 56/371 (15.1%)	• Bleeding 24/375 (6.4%) • Duodenum injury 1/375 (0.3%) • Renal injury 1/375 (0.3%) • Enterotomy 6/375 (1.6%) • Injury to other organs 1/375 (0.3%) • Revision of anastomosis 4/375 (1.1%) • Extensive intra-abdominal adhesion 6/375 (1.6%) • Other events 16/375 (4.3%) • Ureteric, liver, gallbladder vascular injury (0%)
Unexpected intra-abdominal finding related to CD, *n* (%): 279/375 (74.4%)	• Intra-abdominal abscess 33/375 (8.8%) • Enteric fistula 123/375: (30.4%) ◦ 59//375 (15.7%) entero-colic ◦ 35/375 (9.3%) entero-enteric ◦ 12/375 (3.2%) entero-vesicle ◦ 17/375 (4.5%) entero-cutaneous fistula • Small bowel obstruction 123/375 (32.8%)
Skin closure	• Suture 229/375 (61.1%) • Stapled 143/375 (38.1%) • Not stated 3/375 (0.8%)
Duration of operation	Median 128 min (IQR 59)

Discussion

This study analysed data on patients with CD collected as part of the first ESCP international prospective audit. It provided baseline data for both demographics and surgical management across 151 centres in 37 different countries. The key findings were that parenteral nutrition, urgent/expedited operations and UIAEs were associated with a higher risk of postoperative complications.

Table 3 Descriptive details of 30-day postoperative outcome in 375 CD patients.

Admission to critical care unit	70/375 (18.7%)
Planned from the theatre	66/375 (17.6%)
Unplanned from the theatre	2/375 (0.5%)
Unplanned from the ward	2/375 (0.5%)
Postoperative complications classified according to Clavien–Dindo classifications	
Any complication	126/375 (33.6%)
Grade I	39/375 (10.4%)
Grade II	60/375 (16%)
Grade III	33/375 (8.8%)
Grade IV	5/375 (1.3%)
Grade V	None
Specific complications	
Overt anastomotic leak or intra-abdominal pelvic collection	33/375 (8.8%)
Reoperation	22/375 (5.9%)
Surgical site infection	42/375 (11.2%)
Readmission	20/375 (5.3%)

Timing of surgical intervention in CD is a crucial issue [27,28]. Patients operated on in the acute setting are probably those with sepsis or intestinal obstruction; they might therefore have a higher risk of postoperative complications. Attempts should be made to operate on CD patients in elective settings. This will necessitate a well-planned preoperative optimization [8] to prevent deterioration of patients' general health. However, more research on the nature of this, including timing and selection, is needed [28]. Well-timed, well-optimized elective surgery can only be achieved in a setting of close cooperation between inflammatory bowel disease (IBD) surgeon and gastroenterologist.

Parenteral nutrition might reflect the severity of CD. Although disease severity and nutritional status were not collected as part of this audit, parenteral nutrition correlated with low levels of albumin and haemoglobin confirming that those patients were likely to be suffering from malnutrition. The evidence supporting preoperative optimization in patients with CD is increasing [16,27], including multi-model interventions based on detailed diagnostic imaging and close cooperation between a dedicated IBD surgeon and gastroenterologist [17].

UIAEs increased the risk of postoperative complications. This is in line with a recent study [29] which showed that UIAEs were independently associated with increased 30-day mortality, 30-day morbidity and prolonged postoperative LOS. Quality improvement efforts should focus on prevention of these events, mitigation of harm after occurrence of event, and risk/severity-adjusted tracking and benchmarking. UIAEs are defined as any deviation from the ideal intra-operative course

Table 4 Univariate and multivariate logistic regression analyses showing risk factors for postoperative complication in patients with Crohn's disease undergoing right hemicolectomy or ileocaecal resection.

	Univariate analysis			Multivariate analysis		
Co-variates in the model*	Odds ratio	95% CI	*P* value	Odds ratio	95% CI	*P* value
Age	1.02	1–1.03	0.0274	1.01	0.99–1.02	0.4383
Gender: female, male	1.23	0.78–1.94	0.375	0.89	0.55–1.45	0.6386
ASA grade: low grade (I and II), high grade (II and IV)	1.58	0.84–2.98	0.152	1.18	0.57–2.46	0.6505
Smoking status: non-smoker, ex-/current smoker	1.49	0.93–2.38	0.0989	1.29	0.78–2.11	0.3172
Co-morbidity: no, yes	3.67	1.2–11.1	0.0212	2.67	0.81–8.83	0.1075
Preoperative haemoglobin	1.03	0.9–1.18	0.642	1.09	0.94–1.27	0.2363
Low albumin: no, yes	1.02	0.65–1.61	0.932	1.29	0.77–2.14	0.3347
Biologics: no, yes	0.886	0.5–1.58	0.68	0.92	0.51–1.67	0.7919
Parenteral nutrition: no, yes	2.36	1.1–4.97	0.0234	**2.85**	**1.20–6.74**	**0.0173**
Urgency of surgery: elective, urgent/expedited	1.96	1.2–3.22	0.007	**2**	**1.13–3.55**	**0.018**
Surgeon in charge: general, colorectal	0.809	0.45–1.45	0.477	0.92	0.47–1.83	0.819
Access to abdomen: open, intended laparoscopic	0.824	0.52–1.29	0.4	1.19	0.68–2.08	0.5421
Defunctioning/primary stoma: no, yes	0.901	0.45–1.79	0.766	0.98	0.45–2.12	0.9594
Skin closure: suture, stapling	1.61	1–2.56	0.0459	1.27	0.76–2.12	0.3654
UIAE: no, yes	2.51	1.4–4.55	0.00239	**2.31**	**1.20–4.45**	**0.0123**

UIAE, unplanned intra-operative adverse event.
*Only clinically important co-variates are shown.

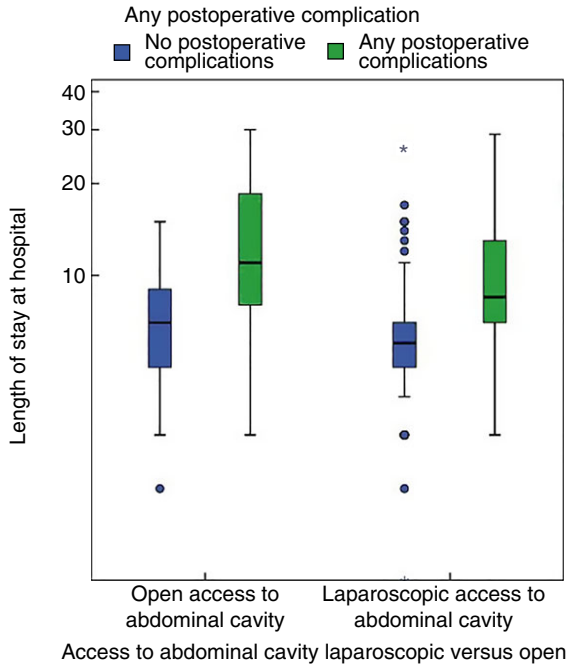


Figure 2 There was a longer length of postoperative stay for patients who were operated via open access to the abdominal cavity compared to those operated via laparoscopic access.

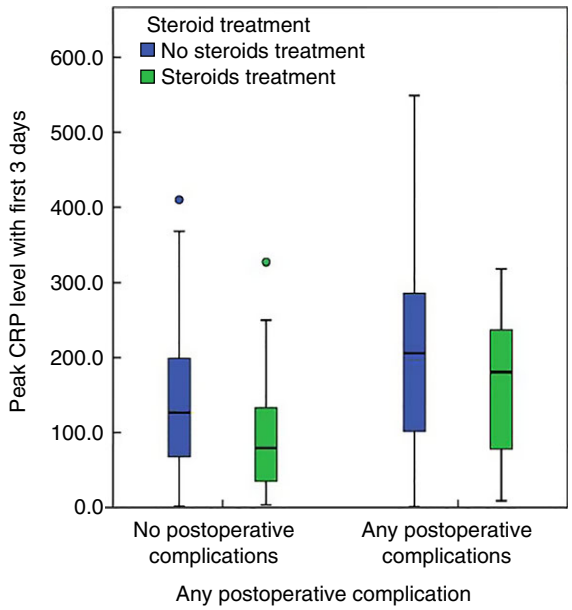


Figure 3 Postoperative complications and C-reactive protein (CRP) peak level within the first 3 postoperative days. Note that treatment with corticosteroids depressed CRP elevation in both groups.

occurring between skin incision and skin closure [30]. Table S2 in the Supporting material shows the details of the UIAEs.

Other risk factors did not have a significant impact on the outcome in this study. Anastomotic type, site, configuration and instrumentation (type of stapler device and suture material) were not associated with any variation in postoperative outcome, but our study size is insufficient to be confident of this finding (Table S1 in the Supporting material provides details of anastomotic technique). Preoperative medical treatment has been debated in the literature, with conflicting results. In this study, its use was not associated with improved or worse outcomes. Biologics dose, duration of treatment, drug bioavailability and neutralizing antibodies are essential factors that may influence postoperative outcome.

The key strengths of this study lie in its cross-sectional and prospective nature which captured contemporaneous and unselected data from 151 sites internationally using a dedicated online system. Although the sample size was relatively low, this study still represents one of the most wide-scale studies in the literature. Another limitation is the lack of detail on other possible confounders, including disease phenotype, severity, preoperative nutritional screening, details of regimes used for nutritional support, duration of medical treatment prior to surgery, duration of postoperative thrombosis prophylaxis and use of steroid stress dose. It must also be noted that this study design cannot ever provide irrefutable evidence on the impact of a particular variable; despite careful multivariable regression modelling we can never fully control for selection bias effects or the hidden confounders and interaction effects inherent in the complex decision making processes that underpin surgical care.

Our study identified that parenteral nutrition, urgent/expedited operations and UIAEs were associated with higher risk of postoperative complications in this population of patients undergoing ileocaecal or right sided resections for Crohn's disease. These findings may highlight the need for enhanced cooperation and communication between members of the IBD multidisciplinary team to improve pathways for patients needing surgical intervention, which might in turn improve outcomes. There is certainly a need for further prospective research in this area; we need to establish the potential benefits bought by delaying urgent surgery where possible, optimizing nutrition and undertaking planned surgery in a more controlled manner upon outcomes for patients.

Conflicts of interest

None declared.

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Supporting Information

Additional Supporting Information may be found in the online version of this article:

Table S1. Univariate and multivariate logistic regression analyses showing possible technical risk factors for anastomotic leak and/or pelvic collection in patients with Crohn's disease undergoing right hemicolectomy or ileo-caecal resection.

Table S2. Unplanned intraoperative adverse events in patients with Crohn's disease undergoing right hemicolectomy or ileo-caecal resection.

Appendix S1. Collaborators.