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National variations in perioperative assessment and surgical management of Crohn's disease: a multicentre study

SICCR Current Status of Crohn's Disease Surgery Collaborative[†]

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Abstract

Aim Crohn's disease (CD) requires a multidisciplinary approach and surgery should be undertaken by dedicated colorectal surgeons with audited outcomes. We present a national, multicentre study, with the aim to collect benchmark data on key performance indicators in CD surgery, to highlight areas where standards of CD surgery excel and to facilitate targeted quality improvement where indicated.

Methods All patients undergoing ileocaecal or redo ileocolic resection in the participating centres for primary and recurrent CD from June 2018 to May 2019 were included. The main objective was to collect national data on hospital volume and practice variations. Postoperative morbidity was the primary outcome. Laparoscopic surgery and stoma rate were the secondary outcomes.

Results In all, 715 patients were included: 457 primary CD and 258 recurrent CD with a postoperative morbidity of 21.6% and 34.7%, respectively. Laparoscopy was used in 83.8% of primary CD compared to 31% of recurrent CD. Twenty-five hospitals participated and

the total number of patients per hospital ranged from 2 to 169. Hospitals performing more than 10 primary CD procedures per year showed a higher adoption of laparoscopy and bowel sparing surgery.

Conclusions There is significant heterogeneity in the number of CD surgeries performed per year nationally in Italy. Our data suggest that high-volume hospitals perform more complex procedures, with a higher adoption of bowel sparing surgery. The rate of laparoscopy in high-volume hospitals is higher for primary CD but not for recurrent CD compared with low-volume hospitals.

Keywords Crohn's disease, inflammatory bowel disease, ileocaecal resection, colorectal surgery, national audit

What does this paper add to the literature?

Twenty-five hospitals participated in this national multicentre study including 715 patients who underwent ileocaecal or redo ileocolic resection for Crohn's disease during a 12-month study period. High-volume hospitals perform more complex procedures, with a higher adoption of bowel sparing surgery.

Introduction

Patients with Crohn's disease (CD) affecting the terminal ileum have a high risk of requiring surgery at least once during their lifetime, with common indications for surgery including abscesses, complex internal fistulas and fibrostenotic strictures [1]. Surgery for CD carries a high risk of complications including wound infections, anastomotic leak and intra-abdominal sepsis, which are made more likely by immune suppression, malnutrition

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and penetrating or recurrent disease. Despite surgery many patients can develop recurrence and require longterm medical treatment and eventually further surgery [2]. For these reasons, patients with CD require a multidisciplinary approach and when surgery is undertaken it should be carried out by colorectal surgeons who are core members of the inflammatory bowel disease (IBD) multidisciplinary team [3] with audited outcomes [4]. Unfortunately many key performance indicators of CD surgery such as postoperative morbidity, rate of ileostomy formation, reoperations and readmissions are not routinely recorded, with paucity of audits on Patient Reported Outcome Measures (PROMs) [5]. We present a national multicentre study promoted by the Italian Society of Colorectal Surgery (SICCR) with the aim of collecting benchmark data to highlight areas where

standards of CD surgery excel or are substandard and to facilitate targeted quality improvement where indicated.

Method

Study settings

The SICCR promoted the snapshot study 'Current Status of Crohn's Disease Surgery', which is a retrospective, multicentre, observational study developed according to the STROBE checklist [6].

The study protocol was developed by the steering committee and independently reviewed and approved by the SICCR research board. Ethical approval was obtained from the promoting centres and every participating centre had a named principal investigator, liaising with the local ethics committee. Obtaining informed consent from the patients was deemed not necessary by the ethics committees in view of the retrospective nature of the study.

Participating centres were invited directly and by an open call published on the SICCR website and also disseminated during a 2-month period via the society newsletter, with reminders sent every 2 weeks.

Eligibility criteria

All consecutive patients (aged 16 or older) undergoing elective or urgent or emergency ileocaecal or redo ileocolic resection for primary and recurrent CD from 1 June 2018 to 31 May 2019 were included. Patients undergoing proctocolectomy, proctectomy or segmental colectomy were excluded from this study. Urgent surgery was defined as any operation occurring within the same unplanned hospital admission for a CD flare-up or new presentation. Emergency surgery was defined as any operation occurring within 48 hours of an acute CD presentation with obstruction, bleeding or perforation.

Study objectives

The main objective of the study was to collect national benchmark data to identify good standards of care and variations. Postoperative morbidity within 30 days of surgery was the primary end-point. Laparoscopic surgery and stoma rate were the secondary outcome measures.

Data collection

Collected data included patients' demographics, Montreal classification, preoperative imaging and medical treatment, indication for surgery, American Society of Anesthesiologists (ASA) grade, operative details such as main procedure

performed and use of strictureplasties, and key performance indicators in CD surgery (ileostomy rate, surgical access and conversion rate, length of hospital stay, 30-day postoperative morbidity, readmissions and reoperations). The presence of a multidisciplinary team, with regular input from gastroenterologists, dietitians and stoma care team, was also documented. Data on the use of PROMs were also collected. Postoperative morbidity was defined as any complication occurring during the hospital stay or within 30 days after surgery, whilst all readmissions were recorded up to 30 days after discharge.

Definition of low-, mid- and high-volume hospitals

There is no standard definition for high-volume IBD surgery hospitals. A UK consensus panel recognized that an IBD unit should be carrying out more than 20 major intra-abdominal IBD operations each year [5]. However, this definition included all IBD related procedures, whilst the focus of our study was CD, with particular reference to primary and recurrent disease. Acknowledging the lack of a widely accepted denotation for a high-volume CD hospital, the steering committee of our study adopted the following definitions: low-volume, 10 or fewer procedures per year; mid-volume, between 11 and 20 procedures per year; high-volume, more than 20 procedures per year.

Statistical analysis

Categorical variables are presented as frequency and percentages, and were compared using the chi-squared test or Fisher's exact test, as appropriate. Continuous variables are presented as mean (\pm standard deviation) or median (range) according to their distribution, and were compared with the use of Student's t test or the Mann–Whitney U test in the case of normal or skewed distribution, respectively. To identify variables associated with binary outcomes, univariate and multivariate logistic regression analyses were performed. Variables having a P value equal to 0.10 or less in the univariate analysis were included in the multiple regression model. The odds ratio with a 95% confidence interval was estimated as a measure of association.

All reported *P* values were two-tailed, and *P* values < 0.05 were considered to be statistically significant. Statistical analysis was performed by using IBM spss Statistics for Windows, version 25.0 (IBM Corp., Armonk, New York, USA).

Results

Twenty-five hospitals participated and 715 patients were included; 457 patients had surgery for primary CD,

whilst 258 patients had surgery for recurrent CD (Table 1). Every hospital was allocated a unique identifier number (ID).

The total number of patients per hospital ranged from 2 to 169, whilst the number of primary CD and recurrent CD procedures ranged from 1 to 99 and from 1 to 70, respectively, as demonstrated in Fig. 1.

Preoperative imaging and medical treatment

In patients undergoing primary CD surgery, MRI was the most commonly applied imaging technique (70.7%). Ultrasound scan (USS) and CT were used in 53.4% and 53.1% of the patients, respectively. Capsule endoscopy was rarely used (1.7%). Data on preoperative medical treatment in the primary surgery group are summarized in Appendix S3.

Similarly, MRI (65.3%) and USS (59.7%) were the most commonly used imaging modalities in patients with recurrent CD, whilst CT and capsule endoscopy were only used in 39.1% and 2.4% of the patients

respectively. Data on preoperative medical treatment in the recurrent surgery group are shown in Appendix S4.

Laparoscopic surgery and stoma rate

The use of laparoscopic surgery differed significantly between primary (83.8%) and recurrent (31%) CD surgery (P < 0.0001). The conversion rate was 8.9% and 13% for primary and recurrent CD surgery, respectively (P = 0.3).

In the group of patients undergoing surgery for primary CD the ileostomy rate was 11.6%, compared to 19.7% in the recurrent CD group (P = 0.0018).

Postoperative morbidity and anastomotic leak rate

Postoperative complications were observed in 99 (21.6%) patients in the primary CD surgery group compared to 86 (34.7%) in the recurrent CD group (P < 0.0001). Clavien–Dindo Grade 3 or higher complications occurred in 37 (8.1%) and 30 (11.6%)

Table I Seven hundred and fifteen included patients.

| | Primary N | % | Recurrent N | % | P value |
|------------------------------|--------------|------|----------------|------|----------|
| Total number | 457 | | 258 | | < 0.0001 |
| M:F ratio | 274:183 | | 131:127 | | 0.02 |
| Age | 41 (16–85) | | 49 (17–80) | | < 0.0001 |
| BMI | 22 (13.5–42) | | 21.7 (15–40.4) | | 0.18 |
| ASA score ≥ 3 | 57 | 12.5 | 45 | 17.4 | 0.06 |
| Urgency of surgery | | | | | |
| Elective | 387 | 84.7 | 219 | 84.9 | 0.86 |
| Urgent | 61 | 13.3 | 35 | 13.5 | 0.19 |
| Emergency | 7 | 1.5 | 4 | 1.5 | 0.91 |
| Preoperative management | | | | | |
| MDT discussion | 306 | 66.9 | 170 | 65.9 | 0.7 |
| Stoma nurse review | 127 | 27.8 | 73 | 28.3 | 0.75 |
| Dietitian review | 128 | 28 | 79 | 30.6 | 0.54 |
| TPN | 46 | 10 | 54 | 20.9 | 0.0001 |
| Preoperative medical treatme | ent | | | | |
| Steroids | 148 | 32.4 | 82 | 33 | 0.86 |
| Immunosuppressors | 51 | 11.1 | 33 | 13.3 | 0.38 |
| Anti-TNF | 69 | 15.1 | 38 | 15.3 | 0.94 |
| Ileostomy | 53 | 11.6 | 49 | 19.7 | 0.003 |
| Laparoscopy | 383 | 83.8 | 77 | 31 | < 0.0001 |
| Conversion to open | 34 | 8.9 | 10 | 13 | 0.38 |
| LOS | 7 (3–95) | | 8 (3–230) | | |
| Complications | 99 | 21.6 | 86 | 34.7 | 0.0001 |
| Clavien–Dindo ≥ 3 | 37 | 8.1 | 30 | 11.6 | 0.11 |
| Reoperations | 19 | 4.1 | 18 | 7.2 | 0.04 |
| Readmissions | 25 | 5.5 | 17 | 6.8 | 0.29 |

Anti-TNF, anti-tumour necrosis factor; ASA, American Society of Anesthesiologists; BMI, body mass index; F, female; LOS, length of hospital stay; M, male; MDT, multidisciplinary team; N, number; TPN, total parenteral nutrition.

Data are expressed as number (%) or median (range).

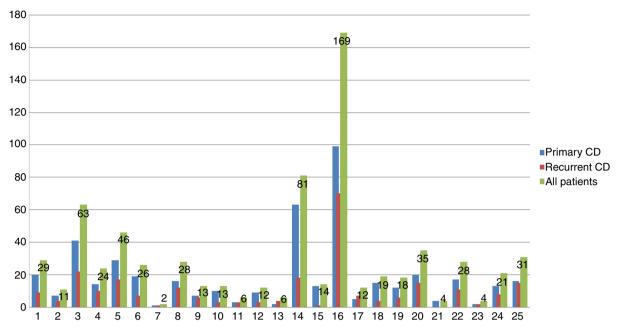


Figure 1 Number of procedures performed in each participating hospital for primary and recurrent Crohn' disease (CD).

patients in the primary CD and recurrent CD group respectively (P=0.11). The anastomotic leak rate was 3.7% in the primary compared to 7.1% in the recurrent CD group (P=0.05). There were 19 reoperations (4.1%) and 25 readmissions (5.5%) in the primary CD surgery group, compared to 18 (7.2%) and 17 (6.8%) in the recurrent CD group (P=0.03 and P=0.42). There was one death (0.2%) in the primary group compared to none in the recurrent.

The hospitals in the upper quartile for number of procedures performed (19.5 procedures for primary CD and 13.5 for recurrent CD, respectively) reported a mean postoperative morbidity of 23.3% ranging from 15.8% to 45% for primary CD and of 37.5% ranging from 17.6% to 53.3% for recurrent CD.

Surgical outcomes according to number of primary CD surgeries performed in each hospital

Ten hospitals (40%) performed 10 or fewer (low volume) primary CD surgeries per year, whilst 11 (44%) performed between 11 and 20 cases per year (mid-volume) and only four (16%) performed more than 20 resections (high volume). Table 2 demonstrates that there was significant heterogeneity in the postoperative morbidity and stoma rate across the 25 participating centres, as shown in Figs 2 and 3.

Laparoscopic surgery (Fig. 4) was used in 64% of the patients in low-volume hospitals, compared to 79.4%

and 91.4% in the mid- and high-volume hospitals, respectively (P < 0.0001).

Forty-five patients (9.8%) had one or more strictureplasties at the same time as the ileocaecal resection. Interestingly, stricture plasties were never used in the patients who had surgery for primary CD in hospitals performing 10 or fewer procedures per year, compared to 13.1% of the patients operated in mid-volume hospitals and 9.5% in high-volume hospitals (P < 0.0001).

At least one additional procedure (strictureplasty, small bowel resection or segmental colectomy) was required at the same time as the ileocaecal resection in 114 patients (24.9%). The rate of required additional procedures according to hospital volume was 8% (low-volume hospitals), 27.4% (mid-volume hospitals) and 26.7% (high-volume hospitals) (P < 0.0001).

Univariate and multivariate analysis for postoperative morbidity and ileostomy formation in primary CD surgery

ASA grade \geq 3 (OR 3.21, 95% CI 1.61–6.39, P=0.001) and the performance of associated surgical procedures (OR 2, 95% CI 1.14–3.52, P=0.015) at the same time as the ileocaecal resection were associated with postoperative complications, as shown in Table 3, whilst a penetrating phenotype of disease (OR 3.32, 95% CI 1.49–7.38, P=0.003) and conversion to open surgery (OR 3.03, 95% CI 1.14–8.05, P=0.026) were

Table 2 Laparoscopy, stoma rate, associated resections and morbidity for primary Crohn's disease surgery in the 25 participating hospitals.

| | | | Stoma | | CONV ASS | | | MORB | | | | |
|-----|-----|-------------|------------|-------------|------------|------------|-------------|------------|-----------|------|-----------|-----------|
| ID | N | PEN | N (%) | LAP $N(\%)$ | N (%) | SXPL | PROC | N (%) | AL | LOS | Reop | Read |
| 7 | 1 | 0 | 0 | 1 (100%) | 0 | 0 | 0 | 1 (100%) | 0 | 6 | 0 | 0 |
| 8 | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 9 | 0 | 0 |
| 14 | 2 | 0 | 0 | 2 (100%) | 0 | 0 | 0 | 1 (50%) | 0 | 6.5 | 0 | 0 |
| 12 | 3 | 2 (66.6%) | 1 (33.3%) | 2 (66.6%) | 0 | 0 | 0 | 0 | 0 | 7 | 0 | 0 |
| 24 | 4 | 1 (25%) | 0 | 4 (100%) | 0 | 0 | 0 | 1 (25%) | 1 | 11.5 | 1 | 0 |
| 20 | 5 | 1 (20%) | 1 (20%) | 2 (40%) | 0 | 0 | 0 | 1 (20%) | 0 | 6 | 0 | 0 |
| 2 | 7 | 1 14.3%) | 0 | 7 (100%) | 0 | 0 | 0 | 1 (14.3%) | 1 | 7 | 1 | 0 |
| 10 | 7 | 3 (42.8%) | 0 | 5 (71.4%) | 0 | 0 | 0 | 2 (28.6%) | 0 | 6 | 0 | 0 |
| 13 | 9 | 1 (11.1%) | 0 | 8 (88.8%) | 0 | 0 | 2 (22.2%) | 0 | 0 | 5 | 0 | 0 |
| 11 | 10 | 3 (30%) | 2 (20%) | 1 (10%) | 0 | 0 | 2 (10%) | 4 (40%) | 2 | 8.5 | 2 | 0 |
| 22 | 12 | 5 (41.7%) | 3 (25%) | 11 (91.7%) | 0 | 1 (8.3%) | 2 (16.7%) | 3 (25%) | 0 | 6 | 1 | 0 |
| 16 | 13 | 5 (38.5%) | 4 (30.8%) | 13 (100%) | 1 (7.7%) | 0 | 0 | 2 (15.4%) | 0 | 6 | 0 | 0 |
| 19 | 13 | 3 (23.1%) | 3 (23.1%) | 9 (69.2%) | 2 (22.2%) | 0 | 0 | 3 (23.1%) | 0 | 7 | 0 | 0 |
| 4 | 14 | 3 (21.4%) | 1 (7.1%) | 13 (92.8%) | 3 (23%) | 2 (14.3%) | 4 (28.7%) | 1 (7.1%) | 1 | 7.5 | 1 | 2 |
| 21 | 15 | 3 (20%) | 0 | 9 (60%) | 2 (22.2%) | 2 (13.3%) | 2 (13.3%) | 1 (6.7%) | 0 | 9 | 0 | 0 |
| 9 | 16 | 7 (43.7%) | 2 (12.5%) | 1 (6.2%) | 0 | 1 (6.2%) | 9 (56.2%) | 2 (12.5%) | 0 | 7.5 | 0 | 0 |
| 18 | 16 | 4 (25%) | 1 (6.2%) | 12 (75%) | 0 | 5 (27.8%) | 8 (50%) | 4 (25%) | 0 | 7 | 0 | 0 |
| 25 | 17 | 9 (52.9%) | 0 | 16 (94.1%) | 3 (18.7%) | 4 (23.5%) | 5 (29.4%) | 4 (23.5%) | 0 | 5 | 2 | 2 |
| 6 | 19 | 3 (15.8%) | 0 | 19 (100%) | 1 (5.3%) | 1 (5.3%) | 2 (10.5%) | 4 (21%) | 2 | 5 | 0 | 1 |
| 1 | 20 | 9 (45%) | 3 (15%) | 19 (95%) | 0 | 4 (20%) | 10 (50%) | 4 (20%) | 1 | 6 | 1 | 4 |
| 23 | 20 | 5 (25%) | 2 (10%) | 17 (85%) | 3 (17.7%) | 3 (15%) | 6 (30%) | 9 (45%) | 3 | 6 | 3 | 2 |
| 5 | 29 | 5 (17.2%) | 0 | 27 (93.1%) | 1 (3.7%) | 2 (6.9%) | 6 (20.7%) | 5 (17.2%) | 0 | 7 | 1 | 3 |
| 3 | 41 | 20 (48.8%) | 4 (9.7%) | 37 (90.2%) | 0 | 10 (24.4%) | 10 (24.4%) | 7 (17%) | 2 | 10 | 1 | 0 |
| 15 | 63 | 2 (3.2%) | 10 (15.9%) | 59 (93.6%) | 4 (6.8%) | 4 (6.3%) | 10 (15.9%) | 10 (15.8%) | 1 | 5 | 1 | 1 |
| 17 | 99 | 38 (38.4%) | 16 (16.1%) | 89 (89.9%) | 14 (15.7%) | 6 (6%) | 36 (36.4%) | 29 (29.3%) | 3 | 8 | 4 | 10 |
| All | 457 | 133 (29.1%) | 53 (11.6%) | 383(83.8%) | 34 (8.9%) | 45 (9.8%) | 114 (24.9%) | 99 (21.6%) | 17 (3.7%) | 7 | 19 (4.1%) | 25 (5.5%) |

AL, anastomotic leak; ASS PROC, associated procedures at the same time as the ileocaecal resection; CONV, conversion to open; LAP, laparoscopy; LOS, length of hospital stay; MORB, morbidity; *N*, number of patients; PEN, penetrating phenotype of disease; Read, readmissions; Reop, reoperations; SXPL, strictureplasties.

associated with ileostomy formation (Table 3). The use of minimally invasive surgery correlated with reduced postoperative morbidity (OR 0.45, 95% CI 0.22–0.92, P=0.03) and stoma rate (OR 0.17, 95% CI 0.07–0.41, P<0.001). There was no correlation with preoperative medical treatments for both outcomes.

Surgical outcomes according to number of recurrent CD surgeries performed in each hospital

Only 24 hospitals performed recurrent CD surgery. Sixteen hospitals (66.6%) performed 10 or fewer (low volume) recurrent CD surgeries per year, whilst six (25%) performed between 11 and 20 cases per year (mid-volume) and only two (8.3%) performed more than 20 resections (high volume).

Table 4 demonstrates the significant heterogeneity in the postoperative morbidity (Fig. 5), use of laparoscopy and stoma rate (Fig. 6) amongst the 24 participating centres.

Differently from primary CD surgery, laparoscopic surgery (Fig. 7) was used in 46.1% of the patients in

low-volume hospitals, compared to 28.4% and 17.4% in the mid- and high-volume hospitals, respectively.

Twenty-nine patients (12.1%) had one or more strictureplasties at the same time as the redo ileocolic resection. Similar to the results of primary CD surgery, stricture-plasties were never used at the same time as the redo ileocolic resections in patients undergoing surgery in low-volume hospitals, compared to 6.8% and 20.6% in mid- and high-volume hospitals, respectively (P < 0.0001).

At least one additional procedure (strictureplasty, small bowel resection or segmental colectomy) was required at the same time as the redo ileocolic resection in 60 patients (23.2%). The rate of required additional procedures was 2.5% in low-volume hospitals, 18.2% in mid-volume hospitals and 34.7% in high-volume hospitals (P < 0.0001).

Univariate and multivariate analysis for postoperative morbidity and ileostomy formation in recurrent CD surgery

Similar to primary CD, the performance of associated surgical procedures (OR 2.82, 95% CI 1.24–4.17,

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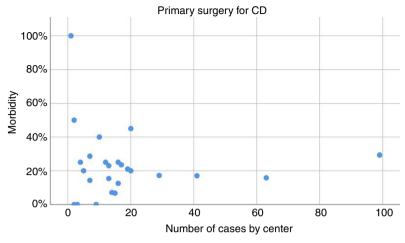


Figure 2 Postoperative morbidity following primary Crohn's disease (CD) surgery in 25 participating Italian hospitals.

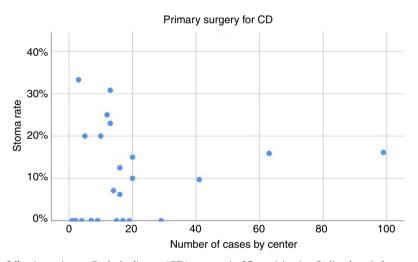


Figure 3 Stoma rate following primary Crohn's disease (CD) surgery in 25 participating Italian hospitals.

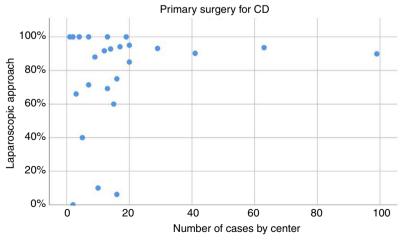


Figure 4 Use of laparoscopy at primary Crohn's disease (CD) surgery in 25 participating Italian hospitals.

Table 3 Univariate and multivariate analysis for postoperative morbidity and ileostomy formation following primary CD.

| | Primary CD – postoperative morbidity | | | | | | Primary CD – stoma formation | | | | | | |
|-------------------------------|--------------------------------------|-------------|-------|-----------------------|-------------|-------|------------------------------|-------------|---------|-----------------------|-------------|---------|--|
| | Univariate analysis | | | Multivariate analysis | | | Univariate analysis | | | Multivariate analysis | | | |
| Variable | OR | 95% CI | P | OR | 95% CI | P | OR | 95% CI | P | OR | 95% CI | P | |
| Age | 1.02 | 1.00-1.03 | 0.035 | 1.00 | 0.98-1.02 | 0.614 | 1.00 | 0.98-1.02 | 0.833 | | | | |
| Sex (female) | 0.80 | 0.49 - 1.28 | 0.358 | | | | 0.87 | 0.47 - 1.57 | 0.646 | | | | |
| BMI | 0.97 | 0.91-1.03 | 0.310 | | | | 0.93 | 0.85 - 1.01 | 0.100 | 0.89 | 0.80-0.98 | 0.023 | |
| ASA grade ≥ 3 | 2.69 | 1.49-4.84 | 0.001 | 3.21 | 1.61-6.39 | 0.001 | 1.87 | 0.90-3.89 | 0.091 | 1.51 | 0.43 - 5.26 | 0.520 | |
| Associated procedures (yes) | 1.95 | 1.19-3.19 | 0.008 | 2.00 | 1.14-3.52 | 0.015 | 1.99 | 1.07-3.60 | 0.025 | 1.57 | 0.70-3.52 | 0.271 | |
| Montreal B = 3 | 1.50 | 0.92-2.43 | 0.100 | 1.32 | 0.75 - 2.31 | 0.332 | 3.02 | 1.68-5.45 | < 0.001 | 3.32 | 1.49-7.38 | 0.003 | |
| Montreal L = 3 | 1.33 | 0.84-2.13 | 0.230 | | | | 1.04 | 0.58 - 1.85 | 0.899 | | | | |
| Perianal disease (yes) | 0.55 | 0.23 - 1.14 | 0.132 | | | | 0.96 | 0.38 - 2.12 | 0.930 | | | | |
| Preoperative steroids (yes) | 1.06 | 0.65-1.71 | 0.815 | | | | 1.30 | 0.71-2.33 | 0.390 | | | | |
| Preoperative | 0.98 | 0.47 - 2.05 | 0.974 | | | | 0.453 | 0.14-1.51 | 0.198 | | | | |
| immunosoppression (yes) | | | | | | | | | | | | | |
| Preoperative biologics (yes) | 0.60 | 0.28 - 1.18 | 0.165 | | | | 0.68 | 0.25 - 1.54 | 0.393 | | | | |
| Access (laparoscopic surgery) | 0.53 | 0.30-0.94 | 0.026 | 0.45 | 0.22-0.92 | 0.030 | 0.23 | 0.12 - 0.43 | < 0.001 | 0.17 | 0.07 – 0.41 | < 0.001 | |
| Conversion (yes) | 2.16 | 1.00-4.45 | 0.040 | 1.85 | 0.83-4.11 | 0.130 | 2.71 | 1.09-6.15 | 0.022 | 3.03 | 1.14-8.05 | 0.026 | |

ASA, American Society of Anesthesiologists; BMI, body mass index; CD, Crohn's disease.

P = 0.007) was associated with postoperative morbidity (Table 5), while a penetrating phenotype of disease (OR 2.67, 95% CI 1.27–5.58, P = 0.09) was associated with ileostomy formation (Table 5). There was no correlation with preoperative medical treatments for both outcomes.

Discussion

Our study demonstrated significant heterogeneity across the 25 participating Italian hospitals in the volume of CD surgery cases performed per year, the short-term surgical outcomes and the adoption of minimally invasive surgery and bowel sparing techniques. It is not surprising to highlight variations in IBD surgical practice as, similarly, the wide range of available treatments for IBD has been shown to result in significant heterogeneity amongst physicians in the use of biologics and combination therapy, confirming the need for standardized pathways for the care of IBD patients [7].

To reduce this variability the SICCR has recently published a national position statement with the aim of standardizing multidisciplinary management and surgical treatment of CD nationally [8], and guidelines of several international societies have been released to optimize CD outcomes (e.g. European Crohn's Colitis Organization [1], the American Society of Colorectal Surgery) [9]. A general aim of guidelines is to reduce variations in practice, by providing evidence-based guidance on the best treatment options with the aim to enhance patients' outcomes. It has been previously reported that hospitals with a high annual IBD volume

have lower in-hospital mortality among surgical IBD patients. This difference seems to be more significant for CD rather than ulcerative colitis [10]. In our study, there was only one death out of the 715 patients undergoing CD surgery (0.14%), highlighting that mortality is not an appropriate benchmark outcome to compare performance across different IBD centres. The large number of patients recruited and the multicentre design are the main strengths of our study, together with the focus on key performance indicators of CD surgery, outcomes which are often not so thoroughly audited as in cancer surgery [11]. Despite the absence of a centralized referral pathway to tertiary IBD units in Italy, our results suggest that high-volume centres are more likely to perform the most complex cases. In fact, we found a 3- to 4-fold increase in high-volume centres compared to low-volume hospitals in the number of patients undergoing associated surgical procedures such as segmental colonic resections and strictureplasties at the time of the ileocaecal or redo ileocolic resection. The assumption of an increased number of more complex procedures performed in high-volume hospitals may also explain the lack of increased use of laparoscopic surgery in recurrent CD, whilst in primary CD surgery it was preferred to open surgery much more commonly in high-volume hospitals, with a 1.5-fold increase compared to hospitals performing fewer than 10 procedures per year. We found a higher risk of postoperative complications following ileocolic resection for recurrent CD, which confirms previously published data suggesting up to a 3-fold increase in the anastomotic leak rate compared to primary CD surgery [12], highlighting the

Table 4 Laparoscopy, stoma rate, associated resections and morbidity for recurrent Crohn's disease surgery in the 24 participating hospitals.

| ID | N | PEN | Stoma N (%) | LAP | CONV | SXPL | ASS PROC | MORB N (%) | AL | LOS | Reop |
|-----|-----|------------|-------------|------------|-----------|------------|------------|------------|-----------|------|-----------|
| 16 | 1 | 1 (100%) | 1 (100%) | 0 (0%) | NA | 0 | 0 | 1 (100%) | 0 | 26 | 0 |
| 7 | 1 | 1 (100%) | 0 (0%) | 0 (0%) | NA | 0 | 0 | 0 (0%) | 0 | 9 | 0 |
| 8 | 2 | 0 | 0 (0%) | 0 | NA | 0 | 0 | 0 (0%) | 0 | 11.5 | 0 |
| 11 | 3 | 2 (66.6%) | 1 (33.3%) | 0 (0%) | NA | 0 | 1 (33.3%) | 0 (0%) | 0 | 8 | 0 |
| 12 | 3 | 0 | 0 (0) | 2 (66.6%) | 0 (0%) | 0 | 0 | 1 (33.3%) | 1 (33.3%) | 8 | 1 (33.3%) |
| 13 | 3 | 1 (33.3%) | 1 (33.3%) | 1 (33.3%) | 0 (0%) | 0 | 1 (33.3%) | 1 (33.3%) | 0 | 11 | 0 |
| 14 | 4 | 0 | 0 (0%) | 4 (100%) | 0 (0%) | 0 | 0 | 0 (0%) | 0 | 7 | 0 |
| 2 | 4 | 0 | 1 (25%) | 1 (25%) | 0 (0%) | 0 | 0 | 0 (0%) | 0 | 8.5 | 0 |
| 21 | 4 | 1 (25%) | 2 (50%) | 0 | NÀ | 0 | 0 | 2 (50%) | 0 | 15.5 | 0 |
| 10 | 6 | 5 (83.3%) | 1 (16.7%) | 2 (33.3%) | 0 | 0 | 0 | 1 (16.7%) | 0 | 6 | 0 |
| 22 | 6 | 0 | 0 (0%) | 4 (66.7%) | 1 (25%) | 2 (33.3%) | 2 (33.3%) | 2 (33.3%) | 1 (16.7%) | 6.5 | 1 (16.7%) |
| 6 | 7 | 2 (28.6%) | 1 (14.3%) | 6 (85.7%) | 0 (0%) | 2 (28.6%) | 3 (42.8%) | 2 (28.6%) | 2 (28.6%) | 4 | 2 (28.6%) |
| 20 | 7 | 3 (42.8%) | 1 (14.3%) | 1 (14.3%) | 0 (0%) | 0 | 3 (42.8%) | 2 (28.6%) | 0 | 6 | 1 (14.3%) |
| 19 | 8 | 1 (12.5%) | 1 (12.5%) | 6 (75%) | 1 (16.6%) | 0 | 0 | 0 | 0 | 6.5 | 0 |
| 1 | 9 | 5 (55.5%) | 1 (11.1%) | 8 (88.9%) | 0 (0%) | 0 | 1 (11.1%) | 5 (55.5%) | 1 (11.1%) | 6 | 1 (11.1%) |
| 4 | 10 | 5 (50%) | 2 (20%) | 1 (10%) | 0 (0%) | 0 | 2 (20%) | 3 (30%) | 1 (10%) | 8 | 1 (10%) |
| 25 | 11 | 5 (45.4%) | 0 (0%) | 7 (63.3%) | 1 (14.3%) | 0 | 1 (9.1%) | 4 (36.4%) | 1 (9.1%) | 5 | 0 |
| 9 | 12 | 2 (16.7%) | 3 (25%) | 0 (0%) | NA | 0 | 2 (16.7%) | 3 (25%) | 1 (8.3%) | 8 | 1 (8.3%) |
| 18 | 15 | 4 (26.7%) | 3 (20%) | 1 (6.7%) | 0 (0%) | 0 | 2 (13.3%) | 5 (33.3%) | 0 | 8 | 0 |
| 23 | 15 | 5 (33.3%) | 7 (46.7%) | 3 (20%) | 2 (66.7%) | 1 (6.7%) | 3 (33.3%) | 8 (53.3%) | 0 | 8 | 0 |
| 5 | 17 | 2 (11.8%) | 2 (11.7%) | 4 (23.5%) | 0 (0%) | 4 (23.5%) | 5 (29.4%) | 3 (17.6%) | 1 (5.9%) | 7 | 1 (5.9%) |
| 15 | 18 | 3 (16.7%) | 6 (33.3%) | 10 (55.5%) | 4 (40%) | 1 (5.5%) | 3 (16.7%) | 5 (27.8%) | 1 (5.5%) | 6 | 0 |
| 3 | 22 | 14 (63.6%) | 0 (0%) | 7 (31.8%) | 0 (0%) | 9 (40.9%) | 11 (50%) | 7 (31.8%) | 1 (4.5%) | 15.5 | 1 (4.5%) |
| 17 | 70 | 23 (32.8%) | 15 (21.4%) | 9 (12.8%) | 1 (11.1%) | 10 (4.3%) | 21 (30%) | 31 (44.3%) | 6 (8.6%) | 8 | 8 (11.4%) |
| All | 248 | 85 (34.3%) | 49(19.7%) | 77 (31%) | 10 (13%) | 29 (11.7%) | 61 (24.6%) | 86 (34.7%) | 17 (7.1%) | 8 | 18 (7.2%) |

AL, anastomotic leak; N, number of patients; PEN, penetrating phenotype of disease; LAP, laparoscopy; CONV, conversion to open; ASS PROC, associated procedures at the same time as the redo ileocolic resection; MORB, morbidity; AL, anastomotic leak; LOS, length of hospital stay; Reop, Reoperations; SXPL, strictureplasties.

need for judicious use of diverting stomas in this group of patients, as indicated by our results demonstrating an ileostomy rate of 19.7% in recurrent CD compared to 11.6% in primary CD.

Certainly, more complex IBD patients are at a higher risk of postoperative complications, obscuring the relationship between procedural volume and postoperative morbidity, as sicker patients may have been referred to surgeons with greatest experience. However, the relationship between surgical volume and postoperative outcomes is probably multifactorial and more complex than simply surgeon experience, as for example high-volume hospitals may have more institution-level-related resources [13]; conversely low-volume hospitals may have less support available from the multidisciplinary team, such as gastroenterologists or dietitians.

The European Society of Coloproctology previously reported the results of a snapshot study including 375 CD patients who underwent surgery in 151 centres over a 2-month period in 37 different countries [14]. The audit excluded patients who underwent additional procedures such as stricture plasties at the time of the surgery. The complication rate was 33.6% and the

stoma rate was 12.3%. The authors reported as key findings of the study that parenteral nutrition, urgent operations and intra-operative complications were associated with a higher risk of postoperative complications.

Our study collected self-reported data from 25 different hospitals to describe the current status of CD surgery in Italy. These hospitals were invited by an open call and newsletter promoted by the SICCR, which we believe somehow selected for participation the hospitals where a dedicated colorectal/IBD team was established, which not necessarily reflects the practice taking place all over Italy and might have left uninvolved other small hospitals not participating in the activities of the national colorectal surgery society. The self-reporting nature of the data may also account for the significant heterogeneity of our results in relation to postoperative morbidity, ranging from 0% to 100%. The risk of information and recall bias is intrinsic to the design of retrospective studies and might have affected those centres needing to manually retrieve data for up to 12 months. Conversely, a more cohesive incidence of postoperative morbidity might have been demonstrated by the hospitals already maintaining a prospective database, in

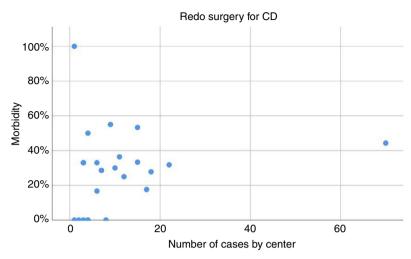


Figure 5 Postoperative morbidity following recurrent Crohn's disease (CD) surgery in 24 participating Italian hospitals.

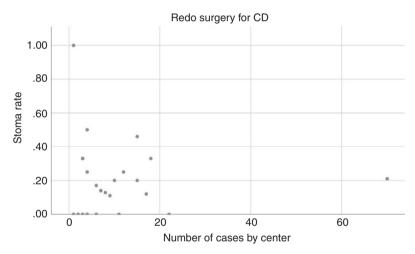


Figure 6 Stoma rate following recurrent Crohn's disease (CD) surgery in 24 participating Italian hospitals.

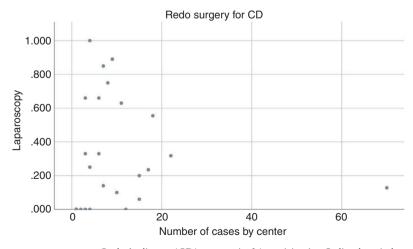


Figure 7 Use of laparoscopy at recurrent Crohn's disease (CD) surgery in 24 participating Italian hospitals.

Table 5 Univariate and multivariate analysis for postoperative morbidity and stoma formation following recurrent CD surgery.

| | Recurre | ent CD – pos | toperativ | e morb | idity | | Recurrent CD – stoma formation | | | | | | | |
|------------------------------|---------------------|--------------|-----------|-----------------------|-------------|-------|--------------------------------|-------------|-------|-----------------------|-------------|--------|--|--|
| | Univariate analysis | | | Multivariate analysis | | | Univariate analysis | | | Multivariate analysis | | | | |
| Variable | OR | 95% CI | P | OR | 95% CI | P | OR | 95% CI | OR | 95% CI | OR | 95% CI | | |
| Age | 0.99 | 0.98-1.01 | 0.562 | | | | 0.96 | 0.48-1.85 | 0.896 | | | | | |
| Sex (female) | 0.84 | 0.49-1.43 | 0.525 | | | | 0.96 | 0.48 - 1.85 | 0.896 | | | | | |
| BMI | 1.00 | 0.93-1.07 | 0.949 | | | | 0.90 | 0.81-0.98 | 0.022 | 0.92 | 0.84 - 1.02 | 0.106 | | |
| ASA grade ≥ 3 | 1.66 | 0.85-3.22 | 0.135 | | | | 1.53 | 0.71 - 3.31 | 0.273 | | | | | |
| Associated procedures (yes) | 2.46 | 1.37-4.40 | 0.002 | 2.82 | 1.24-4.17 | 0.007 | 1.07 | 0.52 - 2.18 | 0.849 | | | | | |
| Montreal B = 3 | 1.77 | 1.02-3.08 | 0.040 | 1.57 | 0.88 - 2.78 | 0.124 | 2.95 | 1.56-5.60 | 0.001 | 2.67 | 1.27-5.58 | 0.009 | | |
| Montreal L = 3 | 0.97 | 0.55 - 1.70 | 0.922 | | | | 1.67 | 0.82 - 3.22 | 0.164 | | | | | |
| Perianal disease (yes) | 1.26 | 0.68-2.30 | 0.453 | | | | 2.05 | 1.03-4.01 | 0.038 | 0.36 | 0.12-0.99 | 0.278 | | |
| Preoperative steroids (yes) | 1.22 | 0.70-2.13 | 0.470 | | | | 1.34 | 0.56-2.95 | 0.481 | | | | | |
| Preoperative | 1.32 | 0.63-2.80 | 0.460 | | | | 0.23 | 0.05 - 1.01 | 0.053 | 0.28 | 0.06-1.30 | 0.106 | | |
| immunosoppression (yes) | | | | | | | | | | | | | | |
| Preoperative biologics (yes) | 1.03 | 0.50-2.13 | 0.925 | | | | 1.34 | 0.56-2.95 | 0.481 | | | | | |
| Access (minimally invasive) | 0.380 | 0.20-0.72 | 0.003 | 0.51 | 0.26-0.99 | 0.050 | 0.21 | 0.08 – 0.55 | 0.002 | 0.35 | 0.13-0.99 | 0.048 | | |
| Conversion (yes) | 0.44 | 0.09-2.12 | 0.309 | | | | 1.13 | 0.23-5.52 | 0.876 | | | | | |

CD, Crohn's disease; BMI, body mass index; ASA, American Society of Anesthesiologists.

keeping with recent literature reporting a postoperative morbidity of 24% following ileocolic CD surgery [15]. The subgroup analysis of the postoperative morbidity we performed for the hospitals in the upper quartile according to number of procedures performed found similar results, reporting an overall morbidity of 23.3% for primary CD and 37.5% for recurrent CD. Nevertheless, this subgroup analysis was outside the objectives and scope of this study, but confirms the need for high quality prospective data. Participation in national and international prospective IBD databases should be implemented into clinical practice as part of a quality improvement programme guided by surgical societies, in order to maintain high standards of practice and to allow local auditing and action when the reported outcomes fall well below these standards.

Urgent action must also be taken to address the lack of standardized PROMs assessment, with approximately 1% of the patients currently being formally evaluated for functional outcomes following CD surgery, as found in our study.

The retrospective nature of the study and the limited number of procedures performed in some hospitals limit our results. These may also explain the relatively low rate of readmission (6%) found in our study compared to 8% in a previously published large case series [16]. Moreover some of the participating centres performed a significant proportion of the 715 included procedures, with one centre for example performing 99 resections for primary CD and 70 for recurrent CD. Nevertheless, the subgroup analysis we performed according to hospital volume was an attempt to evaluate the influence of

single centres on the overall results. There is no agreement on the required number of surgical procedures per year for the definition of a high-volume CD surgery hospital. The minimum number of 20 IBD surgeries per year, suggested by a European consensus group [5], does not take into consideration the multitude of procedures performed in patients with IBD, with the possible implication that units performing many colectomies and ileoanal pouches for ulcerative colitis and only a limited number of CD surgeries might be identified as 'high volume' [17]. The approach adopted in our study, which stratifies hospitals according to the number of procedures performed for the specific operation of ileocolic resection in the setting of primary or recurrent CD, is much more likely to generate meaningful data. The decision on the minimum number of procedures to be performed to achieve acceptable standards in CD surgery should not be based on retrospectively collected data; however, our study supports the hypothesis that the most complex patients may benefit from being cared for in high-volume centres, with the need for confirmation in a mandatory prospective registry.

Conclusions

There is significant heterogeneity in the number of CD surgeries performed per year in each hospital in Italy. Our data suggest that high-volume hospitals perform more complex procedures, with a higher adoption of bowel sparing surgery. The rate of laparoscopy in high-volume hospitals is higher for primary CD but not for recurrent CD compared to low-volume hospitals. A

prospective national CD surgery registry also incorporating PROMs evaluation must be established.

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Conflicts of interest

The authors declare no conflict of interest.

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Supporting Information

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

Appendix S1. SICCR current status of Crohn's disease surgery collaborative. Collaborators and affiliations.

Appendix S2. Statement of contributions.

Appendix S3. Preoperative medical treatment and imaging in patients with primary CD.

Appendix S4. Preoperative medical treatment and imaging in patients with recurrent CD.