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ORIGINAL ARTICLE

Risk factors and predictors of 30-day complications and conversion to open surgery after repeat ileocolic resection of Crohn's disease

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Abstract

Background Repeat ileocolic resection of Crohn's disease (CD) is a challenging procedure that can be followed by a high rate of complications. The present study aimed to identify the factors associated with complications and conversion to open surgery in patients undergoing repeat ileocolic resection for CD.

Methods This was a retrospective review of an IRB-approved prospective database of CD patients who underwent elective repeat ileocolic resection between 2011 and 2021. Univariate and multivariate analyses were performed to determine the predictive factors of postoperative complications and conversion to open surgery.

Results The present study included 65 patients (47.7% male) with a mean age of 52.5 years. 43.1% of patients developed short-term complications, most of which were of Clavien–Dindo class I–II. Longer operative time was found to be an independent predictor of complications (OR 1.016, $p=0.014$). The preoperative use of biological therapy was an independent protective factor from complications (OR 0.243, $p=0.016$). The only significant risk factor of a longer operation time was higher BMI (OR 3.11, $p=0.044$). Overall, 28.1% of laparoscopic procedures were converted to laparotomy. According to bivariate analysis, previous ileocolic open resection (OR 190, $p<0.0001$), longer operation time (OR 1.01; $p=0.036$), and takedown of incidental fistula of incidental fistula (OR 3.78, $p=0.04$) were associated with higher odds of conversion to open surgery.

Conclusion Longer operation time was significantly associated with and predictive of complications after repeat ileocolic resection of CD. Preoperative biological therapy was predictive of a lower rate of complications. Previous ileocolic resection by laparotomy, longer operation time, and takedown of fistula were associated with a higher likelihood of conversion to open surgery.

Keywords Repeat ileocolic resection · Crohn's disease · Complications · Conversion

The management of Crohn's disease (CD) depends on the location, activity, and severity of the disease. Overall, treatment should aim to provide optimal control of the underlying inflammatory process and good quality of life and promote growth in children [1]. Treatment usually starts with medical measures, namely biological anti-tumor necrosis factor (anti-TNF) agents, such as infliximab and adalimumab. Biological treatments have substantially improved treatment in CD patients, from treatment induction to the maintenance of clinical remission in patients with moderate to severe disease [2].

Despite the results conferred by anti-TNF agents, surgery has an integral role in the treatment of active Crohn's disease and its complications. Indications for surgical resection include refractory symptoms to high-dose steroid therapy and complications, such as abscess, stricture, intractable fistula, and toxic megacolon [3]. However, it should be noted

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that surgical resection of the diseased segment is not curative in CD, even after adequate resection.

Therefore, repeat ileocolic resection for CD can be a common practice with varying outcomes, as reported in the literature [4–6]. A meta-analysis of population-based studies found the overall risk of repeat surgery for CD as 28.7% with a 5-year risk of 24.2% and a 10-year risk of 35% [7]. A nationwide analysis of surgery for intestinal CD found that the cumulative incidence of primary (index) surgical intervention for CD has decreased significantly from approximately 58–17% over a 20-year period. In contrast, the rate of repeat surgery for CD remained stable over time [8].

Repeat surgery for CD can be challenging, mainly due to the adhesions from previous surgery, especially if the index operation was undertaken as a laparotomy. We hypothesized that it could potentially be helpful for clinicians to learn about the risk factors of complications associated with repeat surgery to risk stratify their patients and implement additional strategies, if possible, to minimize the incidence of these complications. Therefore, the present study aimed to identify the factors associated with and predictors of complications and conversion to open surgery after repeat ileocolic resection of CD.

Patients and methods

Study design and setting

A retrospective review of an IRB-approved prospective database of patients with Crohn's disease who underwent elective repeat ileocolic resection in the Colorectal Surgery Department of Cleveland Clinic Florida, in the period of 2011 to 2021 was conducted. This study was deemed exempt from Institutional Review Board (IRB) approval based on institutional guidelines and the nature of this study.

Patients' selection

Adult patients of either sex who underwent repeat elective ileocolic resection of Crohn's disease were included. Patients with primary ileocolic resection, patients with diagnoses other than Crohn's disease, and patients with missing follow-up data were excluded.

Data collected

The database was searched and the following information was extracted:

- Patients' demographics: age, sex, body mass index (BMI), weight, American Society of Anesthesiologists (ASA) classification, smoking, and serum albumin levels
- Preoperative therapy: immunosuppressive medications, steroids, and biologics.
- Number and approach of previous ileocolic resections.
- Indication for and approach of surgery (open and laparoscopic, including hand-assisted laparoscopy), operation time, estimated blood loss, conversion to open surgery, additional resections, and takedown of an incidental fistula.
- Complications: number, type, and Clavien–Dindo classification.

Study outcomes and definitions

The primary study outcome was the incidence, type, and predictors of 30-day complications after repeat ileocolic resection of Crohn's disease. Complications were defined as any deviation from the normal expected postoperative course and were graded using the Clavien–Dindo classification [9].

Secondary outcomes included the operation time and factors associated with prolonged operation time and conversion to open surgery. Conversion was defined as the need to do an incision earlier than initially planned to complete the procedure [10].

Addressing bias

All consecutive eligible patients who underwent repeat ileocolic resection of Crohn's disease were included to reduce selection bias. Multiple investigators extracted the data independently to minimize information and measurement bias.

Statistical analysis

Data were analyzed with SPSS™ (IBM Corp; version 23). Continuous data were expressed mean and standard deviation or as median and range. Categorical data were expressed as numbers and proportions. Analysis of continuous data was undertaken by student t test and of categorical data by Fisher exact test or Chi-Square test.

Univariate analysis was used to identify the factors significantly associated with complications and conversion and then they were entered into a multivariate binary logistic regression analysis to determine the independent predictors of these events. The area under the curve (AUC) of the model was calculated to assess the discriminatory ability of the model used. P values < 0.05 indicated significant results.

Table 1 Baseline characteristics of patients

Parameter	Value
Mean age in years	52.5 ± 14.7
Male (%)	31 (47.6)
Mean BMI in kg/m^2	23.5 ± 4
Mean weight in kg	69.2 ± 15.1
Current/former Smoker (%)	19 (29.2)
ASA classification (%)	
I	2 (3.1)
II	56 (86.1)
III	7 (10.8)
Previous open ileocolic resection (%)	25 (38.4)
Mean baseline serum albumin	3.98 ± 0.4
Immunosuppressive drugs (%)	9 (13.8)
Steroids (%)	22 (33.8)
Biologics (%)	29 (44.6)
Indication for surgery (%)	
Stricture	58 (89.2)
Fistula/abscess	7 (10.8)
Approach (%)	
Open	8 (12.3)
Laparoscopic	41 (63.1)
Conversion	16 (24.6)
Mean operation time in minutes	221.5 ± 49.7
Median estimated blood loss in ml	100 (0–1000)
Need for blood transfusion (%)	2 (3.1)
Additional resections (%)	17 (26.1)
Takedown of an incidental fistula (%)	14 (21.5)

BMI body mass index, *ASA* American Society of Anesthesiologists

Results

Patients' characteristics

The present study included 65 patients who underwent repeat ileocolic resection for Crohn's disease. Thirteen (20%) patients had two previous ileocolic resections and 52 (80%) had one previous resection. Thirty-one (47.7%) patients were males with a mean age of 52.5 ± 14.7 years. The baseline characteristics of patients are shown in Table 1. Overall, 13.8% of patients were receiving immunosuppressive drugs before redo surgery, whereas 33.8% were taking steroid therapy and 44.6% have been treated with biological agents. The majority of procedures (87.7%) were started laparoscopically, although 28.1% of the laparoscopic procedures were converted to open surgery. The average operation time was 221.5 min, the median blood loss was 100 (0–1000 ml), and only two patients required blood transfusion. Additional resections were done in 17 (26.1%) patients. The median hospital stay was 5 (range 2–21) days. Nine (13.8%) patients were readmitted and two needed re-intervention for an anastomotic leak.

Type and management of complications

Twenty-eight (43.1%) short-term complications were recorded after redo ileocolic resection. Seven (25%) complications were of Clavien–Dindo class I, 13 (46.4%) of class II, 7 (25%) of class III, and one (3.6%) of class IV. The most common complications were abdominal abscess ($n=8$; 28.6%) and ileus ($n=7$; 25%). Other morbidities included bleeding ($n=2$), venous thrombosis ($n=3$), leakage ($n=3$), enterocutaneous fistula ($n=1$), SBO ($n=1$), urine retention ($n=1$), and surgical site infection ($n=2$). There was no postoperative mortality.

Conservative management was employed for ileus, bleeding, venous thrombosis, and small bowel obstruction. Drainage under the guidance of interventional radiology was performed for abdominal abscess. Reoperation was needed for two patients with anastomotic leakage, one of whom had a redo of the anastomosis and the other of whom underwent loop ileostomy creation. One patient with an enterocutaneous fistula was reoperated on to resect the fistula.

Risk factors and predictors of complications

Overall, 28.6% of patients who developed complications were given biological therapy before surgery compared to 57.6% of patients who did not experience complications ($p=0.04$). Patients who developed complications had a significantly longer mean operation time (238.5 ± 35.3 vs 208.5 ± 43.1 min; $p=0.004$). Although patients who developed complications were older, mostly male, and smokers as compared to patients without complications, these differences were not statistically significant. Also, no significant differences in the preoperative use of immunosuppressive medications, steroids, surgical approach, estimated blood loss, the need for additional resections, and takedown of an incidental fistula were noted between the two groups (Table 2).

On multivariate analysis, the preoperative use of biological therapy was an independent protective factor against complications (OR 0.243, 95%CI 0.077–0.768, $p=0.016$). Prolonged operation time was an independent predictor of complications (OR 1.016, 95%CI 1.003–1.029, $p=0.014$). The AUC of the model was 0.753 with standard error of 0.059, indicating good discriminatory power of the model. Hosmer–Lemeshow had a p value of 0.12, implying a good fit of the data to the model used.

Table 2 Risk factors associated with complications after redo ileocolic resection

Variable		Complications ($n=28$)	No complications ($n=37$)	p value
Patient-related factors	Mean age in years	55.6 ± 16.3	50.1 ± 13.1	0.14
	Male (%)	15 (53.6)	16 (43.2)	0.56
	Mean BMI in kg/m^2	23.1 ± 4.1	23.3 ± 3.9	0.84
	Mean weight in kg	71.6 ± 16.4	67.2 ± 13.8	0.24
	Current/former Smoker (%)	9 (32.1)	10 (27)	0.86
	ASA classification (%)			0.21
	1	1	1	
	2	22	34	
	3	5 (17.8)	2 (5.3)	
	Mean baseline serum albumin	3.9 ± 0.4	4 ± 0.4	0.32
Preoperative medications	Immunosuppressive drugs (%)	4 (14.3)	5 (13.5)	0.9
	Steroids (%)	8 (28.6)	14 (40.5)	0.6
	Biologics (%)	8 (28.6)	21 (56.7)	**0.04**
	Median duration of biological treatment in months (IQR)	30 (4.5, 36)	24 (4.5, 48)	0.933
Operative factors	Indication for surgery (%)			0.9
	Stricture	25 (89.3)	33 (89.2)	
	Fistula/abscess	3 (10.7)	4 (10.8)	
	Previous open ileocolic resection (%)	10 (35.7)	15 (40.5)	0.89
	Number of previous resections (%)			0.36
	One	4 (14.3)	9 (24.3)	
	Two	24 (85.7)	28 (75.7)	
	Median time from previous resection in days (range)	10 (1–30)	14 (1–53)	0.1
	Approach (%)			0.9
	Open	3 (10.7)	5 (13.5)	
	Laparoscopic	18 (64.3)	23 (62.1)	
	Converted laparoscopic to open	7/18 (38.9)	9/23 (39.1)	
	Mean operation time in minutes	238.5 ± 35.3	208.5 ± 43.1	**0.004**
	Median estimated blood loss in ml	100 (0–600)	75 (0–1000)	0.54
	Need for blood transfusion (%)	1 (3.6)	1 (2.7)	0.9
	Additional resections (%)	9 (32.1)	8 (21.6)	0.5
	Takedown of incidental fistula (%)	6 (21.4)	8 (21.6)	0.9

Bold text in p value column signifies statistical significance

BMI body mass index

Factors associated with longer operation time

Using a ROC curve analysis, the cutoff point for operation time at and beyond which the likelihood of complications increased was 192.5 min. Using this cutoff value, patients were classified according to the operation time into two groups: < 192.5 min and ≥ 192.5 min**.** The only significant risk factor for a longer operation time was higher BMI. Using linear regression, higher BMI was associated with higher odds of longer operation time (OR 3.11, $t=2.06$ $p=0.044$). Although older age, male sex, conversion to open surgery, and additional resections were associated with a longer operation time, these associations were not statistically significant (Table 3).

Risk factors and predictors of conversion to open surgery

Overall, 28.1% of laparoscopic procedures needed to be converted to laparotomy. Among 16 patients who had conversion, 15 had significant adhesions and inflammation, whereas in one patient a large phlegmonous bowel segment that could not be extracted through a small incision warranted conversion.

Previous ileocolic resection through a laparotomy, longer operation time, and takedown of an incidental fistula that was otherwise not detected in imaging were factors significantly associated with a higher rate of conversion to open surgery. Age, sex, BMI, ASA classification, preoperative

Table 3 Factors associated with a longer operation time

Variable	Operation time ≥ 192.5 minutes (n = 49)	Operation time < 192.5 min (n = 16)	P Value
Mean age in years	53.8 ± 14.9	48.4 ± 13.7	0.2
Male (%)	25 (51)	6 (37.5)	0.51
Mean body mass index in kg/m^2	24.3 ± 3.8	21.2 ± 3.8	**0.006**
Mean weight in kg	70.8 ± 15.6	63.1 ± 11.2	0.07
Preoperative use of biologics (%)	21 (42.8)	8 (50)	0.83
Indication for surgery (%)			0.9
Stricture	44 (89.8)	14 (87.5)	
Fistula/abscess	5 (10.2)	2 (12.5)	
Number of previous resections (%)			0.9
One	10 (25.6)	3 (18.7)	
Two	39 (74.4)	13 (81.3)	
Open approach (%)	6 (12.2)	2 (12.5)	0.99
Takedown of incidental fistula (%)	12 (24.5)	2 (12.5)	0.48
Conversion (%)	14 (28.6)	2 (12.5)	0.31
Additional resection (%)	15 (30.6)	2 (12.5)	0.2

Bold text in p value column signifies statistical significance

medications, indication for surgery, and additional resections were not significantly associated with conversion (Table 4). According to bivariate analysis, previous ileocolic open resection (OR 190, $p < 0.0001$), longer operation time (OR 1.01; $p = 0.036$), and takedown of incidental fistula of incidental fistula (OR 3.78, $p = 0.04$) were associated with higher odds of conversion to open surgery.

Impact of the surgical approach on the outcomes of redo ileocolic resection

Patients who underwent open ileocolic resection had similar age, sex, BMI, Charlson score, ASA classification, and smoking status to patients who underwent laparoscopic ileocolic resection and patients converted to open surgery. Compared to laparoscopy, open surgery was performed more often for the takedown of fistula and when the previous ileocolic resection was done via a laparotomy (87.5% vs 7.3%). There were no significant differences between the surgical approaches in complications, reoperation, readmission, operation time, or hospital stay (Table 5).

Discussion

Repeat ileocolic resection of Crohn's disease is a technically demanding and challenging procedure that can be associated with considerable rates of complications and conversion to open surgery [11]. This was reinforced by the findings of our study as 43% of patients experienced postoperative morbidities and 28% were converted to laparotomy. These high rates warranted further exploration of the factors associated and predictive of them, which was the main objective of the present study.

Complications and conversion after repeat surgery for Crohn's disease would predictably be higher than those after the primary operation. This observation may be explained by the dense adhesions caused by the previous surgery and inflammation associated with recurrent Crohn's disease that can result in a more challenging operation and higher complication rates, as has been reported before [12].

Although the rate of complications in this study appears to be high, more than 70% of complications were minor of Clavien–Dindo Grade I–II. The most common complications were abdominal abscess and ileus, both are directly pertinent to the nature of the disease and extent of dissection performed in repeat surgery. Notably, only two patients needed a second surgical intervention to treat anastomotic leakage and there was no mortality in this series. Therefore, despite the high complication rate after repeat ileocolic resection, it still can be regarded as a relatively safe procedure since most complications can be managed by conservative and interventional methods.

A longer operation time was significantly associated with a higher complication rate which was consistent with a meta-analysis [13] that found a 14% increase in the likelihood of complications for every 30 min of additional operation time. It is not entirely clear why increased operation time is associated with more complications, yet it appears to be a multifaceted answer. Several factors were implicated in this regard, including prolonged microbial exposure, tissue ischemia and desiccation, blood stasis, endothelial damage,

Table 4 Risk factors associated with conversion to open surgery

Variable		Conversion ($n=16$)	No conversion ($n=41$)	*P*-value	Bivariate odds ratio (95%CI)	*P*-value
Patient-related factors	Mean age in years	53.7 ± 15.7	50.4 ± 14.7	0.46	—	—
	Male (%)	8 (50)	20 (48.8)	0.93	—	—
	Mean BMI in kg/m^2	23.8 ± 3.8	23.3 ± 3.9	0.66	—	—
	Mean weight in kg	70.9 ± 14.4	68.9 ± 14.8	0.65	—	—
	ASA classification (%)				—	—
	1	0	2 (4.9)	0.9		
	2	14 (87.5)	35 (85.4)			
	3	2 (12.5)	4 (9.6)			
	Previous open ileocolic resection (%)	15 (93.7)	3 (7.3)	**< 0.0001**	190 (18.3- 1974)	**< 0.0001**
Preoperative medications	Immunosuppressive drugs (%)	3 (18.7)	5 (12.2)	0.67	—	—
	Steroids (%)	8 (50)	14 (34.2)	0.42	—	—
	Biologics (%)	10 (62.5)	18 (43.9)	0.33	—	—
Operative factors	Indication for surgery (%) Stricture Fistula/abscess	15 (93.7) 1 (6.3)	38 (92.7) 3 (7.3)	0.9	—	—
	Number of previous resections (%)			0.7	—	—
	One	3 (18.7)	6 (14.6)			
	Two	13 (81.3)	35 (85.4)			
	Mean operation time in minutes	247.1 ± 70.1	213.8 ± 37.2	**0.02**	1.014 (1.001- 1.03)	**0.036**
	Additional resections (%)	6 (37.5)	9 (21.9)	0.39	—	—
	Takedown of incidental fistula (%)	7 (43.7)	5 (12.2)	**0.02**	3.78 (1.05- 13.6)	**0.04**

Bold text in p value column signifies statistical significance

BMI body mass index, *ASA* American Society of Anesthesiologists, *CI* confidence interval

increased surgeons' fatigue, and extended anesthesia time. Moreover, longer operation times usually imply more complex or difficult surgeries with which higher rates of complications are expected and the operative times are longer because of intraoperative complications [13–16].

Since longer operation time was found as an independent predictor for complications, we opted to determine its cutoff value, beyond which the complication rate would increase significantly. Only a higher BMI was found to be significantly associated with a longer operation time. Obesity is known to prolong operation time and is a risk factor of short-term postoperative adverse events [17]. An increased surgical time in patients with obesity undergoing colorectal surgery has been reported, as compared to patients with lower BMI [18]. Interestingly, performing additional resections or takedown of an incidentally found fistula did not increase the operation time or complications significantly. This finding further supports performing additional necessary steps during repeat ileocolic resection, knowing that they may not impact the outcomes in a significant manner. Neither did the indication for ileocolic resection nor the number or approach of the previous resection have a tangible impact on complication rate or operation time.

Conversely, the preoperative use of biological agents was found as an independent protective factor against complications. The association between biological agents and the outcome of surgery for Crohn's disease has been a matter of controversy. While some studies [19, 20] reported higher postoperative complications when biological agents were used, other authors failed to find an association between biological therapy and complications after ileocolic resection of Crohn's disease [21, 22]. It is worthy to note that these studies were mainly assessing outcomes after primary ileocolic resection, rather than after repeat resection. It is possible that biological therapy may reduce the extent of inflammation associated with recurrent Crohn's disease and thus make the surgical procedure

Table 5 Impact of surgical approach on the outcome of redo ileocolic resection

Factor	Group	Open ($n=8$)	Laparoscopic ($n=41$)	Laparoscopic converted to open ($n=16$)	p value
Mean age years (SD)		60.25 (10.70)	50.44 (14.69)	53.75 (15.70)	0.209
Sex (%)	Male	3 (37.5)	20 (48.8)	8 (50.0)	0.824
	Female	5 (62.5)	21 (51.2)	8 (50.0)	
Mean BMI in kg/m^2 (SD)		24.60 (4.98)	23.27 (3.93)	23.76 (3.85)	0.679
Charlson score (%)	1	1 (20.0)	1 (10.0)	3 (75.0)	0.094
	2	2 (40.0)	5 (50.0)	0 (0.0)	
	3	2 (40.0)	1 (10.0)	1 (25.0)	
	4	0 (0.0)	3 (30.0)	0 (0.0)	
ASA (%)	1	0 (0.0)	2 (4.9)	0 (0.0)	0.864
	2	7 (87.5)	35 (85.4)	14 (87.5)	
	3	1 (12.5)	4 (9.8)	2 (12.5)	
Smoking status (%)	None	4 (50.0)	31 (75.6)	11 (68.8)	0.307
	Current	1 (12.5)	2 (4.9)	3 (18.8)	
	Former	3 (37.5)	8 (19.5)	2 (12.5)	
Indication for surgery (%)	Stricture	5 (62.5)	38 (92.7)	15 (93.8)	**0.033**
	Fistula/abscess	3 (37.5)	3 (7.3)	1 (6.2)	
Previous surgery (%)	Laparoscopic	1 (12.5)	38 (92.7)	1 (6.2)	**< 0.001**
	Open	7 (87.5)	3 (7.3)	15 (93.8)	
Biologics (%)		1 (12.5)	18 (43.9)	10 (62.5)	0.067
Complications (%)		3 (37.5)	18 (43.9)	7 (43.8)	0.944
Major complications (%)		1 (12.5)	5 (12.2)	2 (12.5)	0.999
Reoperation (%)		0 (0.0)	1 (2.4)	1 (6.2)	0.654
Readmission (%)		1 (12.5)	5 (12.2)	3 (18.8)	0.807
Median stay in days [range]		5 [4, 13]	5 [2, 21]	5 [3, 14]	0.338
Mean operation time in minutes (SD)		209.38 (45.88)	213.80 (37.19)	247.12 (70.08)	0.055
Additional resections (%)		2 (25.0)	9 (22.0)	6 (37.5)	0.485

Bold text in p value column signifies statistical significance

SD standard deviation, *BMI* body mass index, *ASA* American Society of Anesthesiologists

easier with less dissection required; however, this needs further investigations to confirm.

The seemingly high rate of conversion in our series (28%) was caused by significant adhesions in the vast majority of converted patients. A previous ileocolic resection by laparotomy was a strong independent predictor of conversion when the subsequent surgery was started laparoscopically. This finding is completely understandable since laparotomy is known to be followed by significant and marked intra-abdominal adhesions as compared to laparoscopy [23]. A longer operation time was also significantly associated with a higher conversion rate since it reflects a lack of adequate progress and a complex procedure that may not be safely completed by laparoscopy. Resection of an incidentally found fistula also contributed to a higher rate of conversion, probably owing to the significant adhesions and extensive dissection required to excise such fistulas.

It is important to highlight that the current study is in accord with previous reports confirming the safety of repeat ileocolic resection. According to our results, 12.3% of patients experienced major complications, which is within the range of major complication (6–13.7%) reported by previous studies [24–26]. However, patients with a history of previous laparotomy had higher odds of conversion and longer operative time. The same finding was confirmed by other authors who reported a longer operating time of laparoscopic redo ileocolic resection for Crohn's disease is in patients with previous multiple laparotomies [27]. While this finding does not preclude the safety of laparoscopic redo ileocolic resection, it allows preoperative informed consent in patients who had their previous resection by laparotomy as they might have an increased risk of conversion to open surgery.

The present study has some limitations that include its retrospective and single-center nature which may be associated with selection bias. Also, the small numbers analyzed

are another limitation, although this series represents one of the largest cohorts of repeat ileocolic resections in CD patients. Furthermore, we were able to identify some of the factors associated with the outcomes studies. Larger multicenter prospective studies are needed to ascertain the findings of the present study.

Conclusion

Longer operation time was significantly associated with and predictive of complications after repeat ileocolic resection of Crohn's disease, whereas preoperative biological therapy was predictive of a lower rate of complications. Increased BMI was associated with longer operation time. Previous ileocolic resection by laparotomy, longer operation times, and takedown of an incidentally found fistula were significantly associated with higher conversion to open surgery.

Author contributions SE designed the study. MF and NH collected and interpreted the data. SE performed the data analysis and interpretation. SE wrote the manuscript. MF, NH, ZG, ESA, and RG critically revised the manuscript. SW reviewed the protocol and initial results of the study and critically revised the manuscript. All authors critically reviewed the manuscript and approved the final version.

Declarations

Disclosure Sameh Emile, Michael Freund, Nir Horesh, Zoe Garoufalia, Rachel Gefen, Emanuela Silva-Alvarnega, and Steven Wexner have no relevant conflicts of interest to be disclosed.

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