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ORIGINAL ARTICLE

Mortality Is Rare Following Elective and Non-elective Surgery for Ulcerative Colitis, but Mild Postoperative Complications Are Common

Joseph D. Feuerstein[1] · Thomas Curran[2] · Michael Alosilla[2] · Thomas Cataldo[3] · Kenneth R. Falchuk[1] · Vitaliy Poylin[3]

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Abstract

Background Data Currently, data regarding the rates of morbidity and mortality following non-elective colectomy for ulcerative colitis (UC) are variable. We sought to determine the rates and predictors of 90-day mortality and complications following colectomy for UC.

Methods Patients undergoing an initial surgery for UC at a tertiary care center between January 2002 and January 2014 were included. Patients were identified using ICD-9 code 556.x. Each record was manually reviewed for demographic information, medical histories, UC history, medications, and data regarding the admission and discharge. Charts were reviewed for mortality and complications within 90 days of surgery. Complications were classified using the Clavien–Dindo classification system. Univariate and multivariate analyses were performed using IBM SPSS Statistics, version 23.0.

Results Two hundred and fifty-eight patients underwent surgery for UC. 69% were elective, and 31% were urgent/emergent. There were no deaths reported within 30 days of surgery. At 90 days, there were 2 deaths in the elective group and 1 death in the urgent/emergent group. The death in the urgent/emergent group was likely related to the initial surgery, while the elective group death was not directly related to the initial surgery for UC. Complications occurred in 47% of patients. There were no significant differences in rates of complications in either surgical cohort. Majority (62%) of the complications were Clavien–Dindo grade 1 or 2 with no difference in the elective or urgent/emergent group. Unplanned readmissions occurred in 24% of cases.

Conclusion Surgery for UC is not associated with any mortality at 30 days and very low mortality at 90 days. However, surgery is associated with an increased rate of minor postoperative complications and readmissions.

Keywords Ulcerative colitis · Surgery · Colectomy · Mortality · Complications · Inflammatory bowel disease · Quality

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✉ Joseph D. Feuerstein
jfeuerst@bidmc.harvard.edu

Thomas Curran
thomascurran27@gmail.com

Michael Alosilla
michael.alosilla@gmail.com

Thomas Cataldo
tcatald1@bidmc.harvard.edu

Kenneth R. Falchuk
kfalchuk@bidmc.harvard.edu

Vitaliy Poylin
vpoylin@bidmc.harvard.edu

[1] Department of Medicine and Division of Gastroenterology, Beth Israel Deaconess Medical Center, Harvard Medical School, 110 Francis Street 8E Gastroenterology, Boston, MA 02215, USA

[2] Department of Surgery, Beth Israel Deaconess Medical Center, Harvard Medical School, Boston, MA, USA

[3] Department of Surgery and Division of Colorectal Surgery, Beth Israel Deaconess Medical Center, Harvard Medical School, Boston, MA, USA

Introduction

Ulcerative colitis (UC) is a chronic inflammatory condition that is typically treated pharmacologically. However, up to 20% of patients will develop severe colitis requiring hospitalization and up to 25% of patients may require surgery during the course of their disease [1]. Surgery is utilized in cases of disease that is refractory to medical therapy, disease complications (e.g., toxic colitis, perforation, uncontrolled hemorrhage), or the presence of dysplasia or cancer [2, 3].

Prior studies have indicated variable rates of mortality associated with surgery for UC with higher rates in patients undergoing emergent surgery ranging from 2.4 to 13.1% compared to rates of 0.6–2.2% in elective surgery [4–10]. Some variability in mortality may be related to older studies and differences in surgical technique over time. Additionally, many studies are from tertiary care referral centers which may result in a bias from sicker patients leading to higher reported mortality rate. While it appears that overall mortality is decreasing in patients undergoing colectomy for UC, a large meta-analysis found that mortality was more common following emergent surgery (5.3% 95% CI 3.8–7.4%) compared to elective surgery (0.7% 95% CI 0.6–0.9%) [9]. However, these data were still limited by the included studies, many of which were from tertiary care centers and from national databases lacking details on each individual patient.

Complications are also an important factor in deciding between continuing pharmacologic therapy versus surgery as well as in determining the surgical approach (e.g., anastomosis vs no anastomosis). Similar to mortality, studies have reported variable rates of complications following surgery for UC ranging from 27 to 61% [11–14]. A large population database study from Calgary reported a complication rate of 61% in patients undergoing colectomy for UC [14]. Surprisingly, these rates were higher in the elective cohort compared to the emergent cohort (64.9 vs 55.4% $p = 0.021$) [14]. Complications were more frequently seen in elderly patients and those with multiple comorbidities [14]. However, lower complication rates of 30% have been reported in the USA [10]. The exact cause of this difference in reported complications is unclear, but referral bias as well as older studies reflecting open, as opposed to more current minimally invasive, surgical approach may have contributed. Additionally, there were significant variations in how complications were defined from study to study [11, 13, 15].

Based on this variability of the current rates of morbidity and mortality following surgery for UC, we sought to determine the 90-day rates of mortality and complications classified by the Clavien–Dindo postoperative surgical complication system following surgery for UC in a tertiary care referral center.

Methods

This is a single-center retrospective cohort study performed at a tertiary care academic medical center, Beth Israel Deaconess Medical Center (BIDMC). The center has a large gastroenterology and colorectal surgery practice and a specialized center for inflammatory bowel disease (IBD). The hospital utilizes an electronic health record system (EHR) from which all the data were collected.

Inclusion Criteria

All records with a hospital discharge International Classification of Disease-9 (ICD-9) code 556.x between January 1, 2002, and January 1, 2014, were reviewed to determine if the patient underwent surgery for UC during the admission. Only patients who underwent one of the following surgical procedures were included in the study: total proctocolectomy and end ileostomy, abdominal colectomy with end ileostomy, proctocolectomy with ileoanal pouch anastomosis (IPAA) formation and diverting ileostomy, one-stage IPAA (j-pouch), or abdominal colectomy with ileorectal anastomosis. Only the initial surgical procedure was included in this study with follow-up surgeries including proctectomy with IPAA formation and ileostomy take down excluded from the analysis.

Exclusion Criteria

Non-UC-related colitis including Crohn's disease, ischemic colitis, and infectious colitis was excluded.

Chart Review

Each chart was reviewed manually by two authors (MA and JDF). Patient demographics, age, gender, ethnicity, highest level of education, and type of medical insurance were collected. UC-related history including duration of disease, prior medications and past medical history, and Charlson comorbidity index was noted. Information related to the admission including admission laboratories, body mass index, medications, systemic steroids (intravenous vs oral), ASA class, indication for surgery, type of surgery, clinical data, and operative details and discharge details was all reviewed. Biologics included infliximab, adalimumab, golimumab, and vedolizumab. Current use of biologics was defined as use of infliximab or vedolizumab within 8 weeks of admission or within 4 weeks of admission for adalimumab and golimumab. Disease severity and fulminant colitis were defined based on Truelove and Witts criteria [16]. Fulminant colitis was defined as a combination of signs and symptoms including those with more than ≥ 10 bowel movements per

day, ongoing bleeding, toxicity, abdominal tenderness, blood transfusions, or colonic dilation on abdominal films [17]. Surgery was classified as urgent/emergent or elective based on the urgency of the procedure according to the notes in the EHR. Charts were then reviewed for any complications or death within 90 days of the initial surgical procedures. Complications were classified using the Clavien–Dindo classification system (Supplemental Table 1). Time to complication was determined by the first complication reported following surgery. Only complications related to the initial surgery were considered for this manuscript. Readmissions were reviewed to determine the time to readmission and cause for the readmission. All complications and mortality were assessed to determine if they were related to the surgery or not by three authors (MA, JDF, and VP). Any disagreements related to if a complication or mortality was related to surgery were reconciled using a modified Delphi method with senior author (VP) making the final decision [18]. Study data were collected and managed using REDCap electronic data capture tools hosted at BIDMC [19].

End Points

The primary end point was mortality at 90 days following initial colectomy for UC. Secondary analysis included the rate and predictors of complications at 90 days following surgery for UC.

Statistical Analysis

Patients experiencing death or complication were compared to those that did not. Two-tailed p values were calculated by Chi-square test for categorical variables or Student's t test for continuous variables. Independent predictors of complication were identified using logistic regression. All variables with a p value less than 0.1 on bivariate comparison of those with complications versus those that did not were included in the model. Backward stepwise elimination was used to determine final independent predictors with variables eliminated for p value greater than 0.05. All analyses were performed using IBM SPSS Statistics, version 23.0 (IBM Corp., Armonk, New York).

The study was approved by the Institutional Review Board at BIDMC.

Results

Two hundred and fifty-eight patients underwent an initial surgery for UC. Of these, 69% (177) of cases were elective and 31% (81) were urgent/emergent (Fig. 1). There were several variables that were different between the elective and the urgent/emergent cohorts (Table 1). Compared to non-elective cases, patients undergoing elective surgery were older (median 45.4 vs 41.4 $p = 0.048$), had higher BMI (26.4 vs 23.1 p 0.003), and had higher Charlson comorbidity index (0.4 vs 0.1 $p = 0.008$), but were less likely to have been on outpatient prednisone (59 vs 84% $p < 0.001$). During the admission, patients who underwent an elective operation were less likely to have a flare of UC on admission (65 vs 95% $p < 0.001$) and less likely to receive intravenous steroids (53 vs 85% $p < 0.001$). Surgical indications ($p < 0.001$), specific surgical procedure ($p < 0.001$), number of stages planned ($p < 0.001$), and ASA class ($p < 0.001$) were all different between the elective and urgent/emergent cohorts. For additional demographic variables and other significant variables see Table 1.

There were no deaths reported in our cohort at 30 days. At 90 days, there were 3 deaths: 2 in the elective group and 1 in the urgent/emergent group. The cause of death in the urgent/emergent group patient was fatal immune-mediated enteritis 47 days after surgery. While not directly related to the surgery, this was considered to be likely related to her recent ulcerative colitis [20]. In the elective cohort, one patient died from unknown causes at home. A second patient died secondary to sepsis after developing a small perforation at her ileostomy site 56 days after surgery. None of the deaths were determined to be directly related to the initial surgery for UC. See supplemental Table 2 for details of the deaths.

Complications developed in 47% ($n = 122$) of the entire cohort with 44% in the elective cohort and 54% in the urgent/emergent cohort (Table 2). There was no difference in time to complication based on elective vs urgent/emergent surgery (Fig. 2). Gastrointestinal issues were the most frequently reported complication followed by infectious complications, but there was no difference in the surgical cohorts in any of the complications. 62% of the complications were Clavien–Dindo grade 1 or 2 with no difference between the cohorts (Table 2). There was no significant difference in any Clavien–Dindo grade complications in the elective or urgent/emergent cohorts (Table 2). Readmissions were seen in 24% of the cohort, with no significant difference seen in the two cohorts ($p = 0.636$) (Table 2). Time to readmission between the groups was different with patients in the elective group readmitted within a mean of 19 days compared to 30.5 days in the urgent/emergent cohort ($p = 0.003$) (Fig. 3). The median readmission hospitalization was 3.5 days (range 1–23).

When comparing predictors of complications Clavien–Dindo grade 3 or higher, univariate predictors with p value < 0.1 include age, female gender, any anastomosis, ASA class, history of myocardial infarction, peptic ulcer disease history, thiopurine use on admission, and adalimumab use on admission. See supplemental Table 3 for a full list of variables. On multivariate analysis, predictors of complications Clavien–Dindo grade 3 or higher

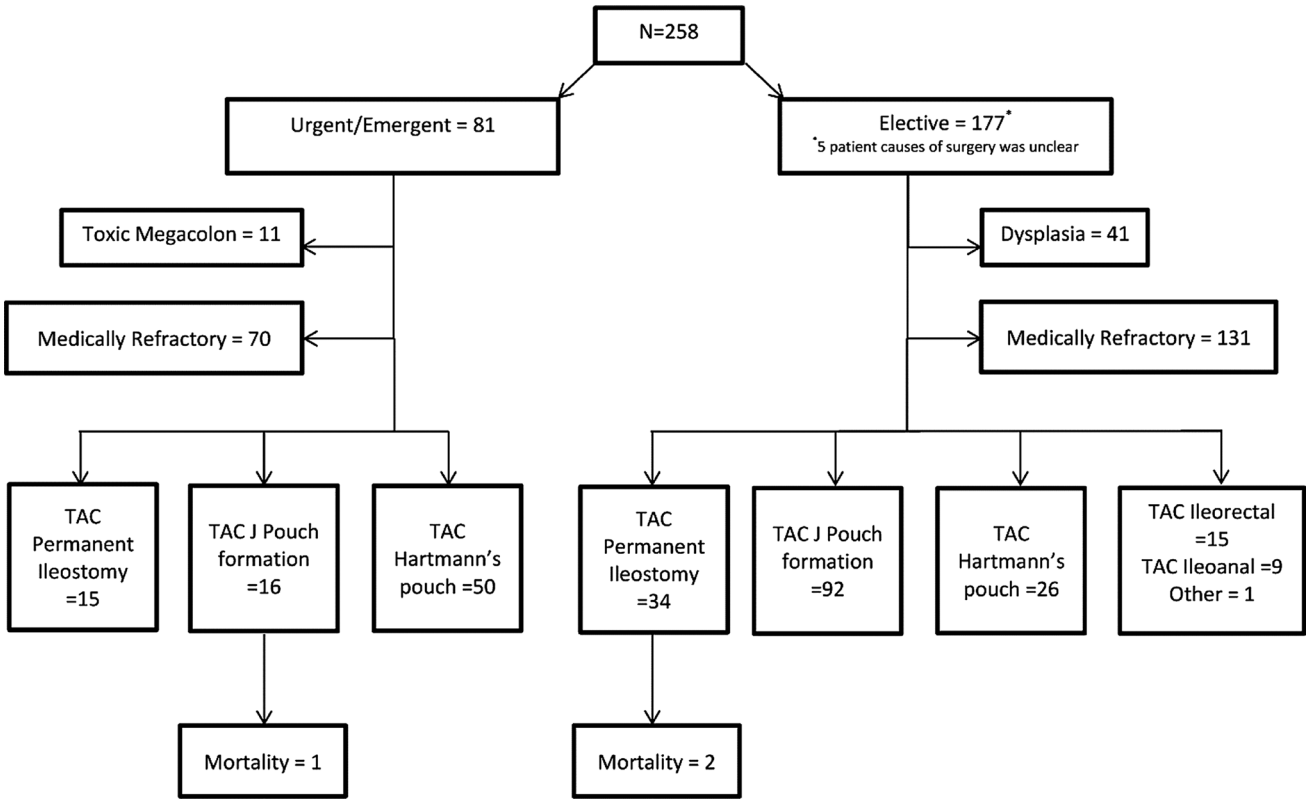

Fig. 1 Patients stratified by type of surgery

included prior myocardial infarction (OR 6.093 95% CI 1.479–25.094), thiopurine use on admission (OR 5.200 95% CI 2.346–11.525), adalimumab use on admission (OR 5.516 95% CI 1.622–18.761), and ASA class 3 or greater (OR 3.014 95% CI 1.387–6.551) (Table 3).

Discussion

The risk of death from surgery for ulcerative colitis is an extremely rare event at a tertiary care academic referral center. None of the deaths were believed to be directly related to the initial surgery (Table 2). In contrast, complications following surgery are not uncommon, occurring in up to 47% of cases. However, the majority of these complications are classified as Clavien–Dindo grade 1 or 2, which by definition are managed without the need for any major interventions. Readmissions, however, remain a concern following surgery for UC in nearly 25% of patients. In general, these readmissions are limited hospital stays of 3.5 days. The exact predictors of complications and readmissions remain elusive, but in our study, prior use of thiopurine, anti-tumor necrosis factor, a personal history of a prior myocardial infarction, and ASA class 3 or higher all increased the risk of a Clavien–Dindo complication grade 3 or greater. Finally, even with potential delays in surgery, urgent/emergent surgery does not carry a higher risk of complications compared to elective surgery.

Prior studies have indicated variable rates of mortality following surgery for UC [4–9]. Some studies have reported higher mortality following urgent/emergent surgery when patients are sicker and likely at greater risk of having complications, but this finding has not been substantiated in all studies [4–9]. Theoretically, patients seen in tertiary care academic referral centers may be sicker and as more patients are treated with infliximab even in community hospitals, the patients being seen in an academic referral center may be at higher risk of death from surgery [14]. However, our study indicates that even with different colorectal surgeons and a study period spanning 12 years, still not a single patient died within 30 days of discharge from their surgical procedure. Additionally, in the three deaths reported within 90 days, none were considered to be directly related to the initial surgery. Our study indicates that even with potentially sicker patients being referred to an academic medical center, still death related to surgery for UC should be seen in < 1% of cases.

While surgical complications can increase the overall cost of care, some complications may be unavoidable [21]. Interestingly, in our study, there was no significant difference in

Table 1 Demographics

Variables	Total $N = 258$	Elective $N = 177$	Urgent/emergent $N = 81$	p Value
Age (SD)	44.2 (15.4)	45.4 (15.2)	41.4 (15.5)	0.048
Males	137 (53)	95 (54)	42 (52)	0.790
Caucasians	234 (94)	162 (94)	72 (90)	0.163
Insurance type				0.183
Private	205 (80)	145 (82)	60 (74)	
Public	49 (19)	30 (17)	19 (24)	
Self-pay	3 (1)	1 (1)	2 (3)	
College education	155 (77)	103 (77)	52 (75)	0.729
Former smoker	62 (24)	45 (26)	17 (22)	0.531
Charlson comorbidity index, mean (SD)	0.3 (0.8)	0.4 (0.9)	0.1 (0.4)	0.008
Total number of medical problems	4.0 (2.6)	4.0 (2.6)	4.1 (2.7)	0.625
Median follow-up, months, mean (SD)	41.6 (42.0)	43.2 (44.5)	38.0 (35.9)	0.319
Outside hospital transfer	20 (8)	2 (1)	18 (23)	< 0.001
Length of stay, days, mean (SD)	9.7 (7.7)	7.1 (4.3)	15.4 (10.1)	< 0.001
Disposition				0.023
Home	14 (6)	12 (7)	2 (3)	
Home with services	221 (89)	154 (90)	67 (87)	
Rehabilitation center	13 (5)	5 (3)	8 (10)	
Days from admission to surgery (excluding same-day surgery)	2.3 (4.8)	0.4 (1.7)	6.4 (6.6)	< 0.001
Duration of disease, years, mean (SD)	9.5 (9.4)	9.7 (9.3)	9.0 (9.9)	0.616
Extent of disease pancolitis	162 (63)	106 (60)	56 (69)	0.167
Extent of disease left sided	53 (21)	43 (24)	10 (12)	0.031
Extent of disease proctosigmoiditis	36 (14)	23 (13)	13 (16)	0.563
Extent of disease proctitis	7 (3)	5 (3)	2 (3)	1.000
Flare on admission	189 (75)	112 (65)	77 (95)	< 0.001
Duration of flare				< 0.001
< 2 weeks	9 (5)	1 (1)	8 (11)	
2–4 weeks	23 (13)	5 (5)	18 (24)	
> 4 weeks	152 (83)	102 (94)	50 (66)	
C-reactive protein (CRP) on admission	73.5 (78.9)	44.9 (33.5)	82.7 (87.3)	0.106
Sedimentation rate (ESR) on admission	38.7 (28.5)	36.1 (29.6)	40.3 (28.7)	0.738
Body mass index (BMI) on admission	25.2 (5.8)	26.4 (6.3)	23.1 (4.1)	0.003
Venous thromboembolism prophylaxis	137 (99)	92 (99)	45 (100)	1.000
Clostridium difficile on admission	6 (2)	3 (2)	3 (4)	0.382
Cytomegalovirus infection	4 (2)	1 (1)	3 (4)	0.093
Total number of medications on admission, mean (SD)	4.5 (3.3)	4.3 (2.9)	5.1 (3.9)	0.071
Home medications oral steroids	173 (67)	105 (59)	68 (84)	< 0.001
Home medications mesalamine	153 (59)	102 (58)	51 (63)	0.495
Home medications thiopurine	63 (24)	48 (76)	15 (19)	0.161
Home medications biologic	79 (30)	57 (32)	22 (27)	0.468
Prior biologic therapy	143 (55)	104 (59)	39 (48)	0.138
Length of steroids				0.014
30 days	105 (64)	70 (73)	35 (51)	
> 30	55 (33)	24 (25)	31 (45)	
< 7	5 (3)	2 (2)	3 (4)	
Steroid dependent at time of admission	43 (22)	35 (26)	8 (13)	0.061
Inpatient IV steroids	163 (63)	94 (53)	69 (85)	< 0.001
Colorectal surgeon				0.115
A	52 (20)	34 (19)	18 (22)	

Table 1 (continued)

Variables	Total $N = 258$	Elective $N = 177$	Urgent/emergent $N = 81$	p Value
B	12 (5)	7 (4)	5 (6)	
C	36 (14)	20 (11)	16 (20)	
D	132 (51)	100 (57)	32 (40)	
Other surgeon	26 (10)	16 (9)	10 (12)	
Laparoscopic	84 (33)	62 (35)	22 (27)	0.253
Surgical indication				< 0.001
Dysplasia/cancer	41 (16)	41 (24)	0 (0)	
Medically refractory	201 (79)	131 (76)	70 (86)	
Toxic megacolon/perforation	11 (4)	0 (0)	11 (14)	
Surgical approach				1.000
Any anastomosis	209 (81)	143 (81)	66 (81)	
No anastomosis	49 (19)	34 (19)	15 (19)	
Surgical procedure				< 0.001
TAC and end ileostomy	76 (30)	26 (15)	50 (62)	
TPC with diverting ileostomy and j-pouch	108 (42)	92 (52)	16 (20)	
TPC and permanent ileostomy	49 (19)	34 (19)	15 (19)	
TPC with j-pouch, no diversion	9 (4)	9 (5)	0 (0)	
TAC and ileorectal anastomosis	15 (6)	15 (9)	0 (0)	
Partial colectomy	1 (0)	1 (1)	0 (0)	
Intraoperative complications	8 (3)	5 (3)	3 (4)	0.709
History of prior abdominal surgery	39 (15)	26 (15)	13 (16)	0.852
ASA class				< 0.001
1	1 (0)	0 (0)	1 (1)	
2	160 (63)	138 (80)	22 (27)	
3	87 (34)	35 (20)	52 (64)	
4	6 (2)	0 (0)	6 (7)	

TAC total abdominal colectomy, *TPC* total proctocolectomy

the likelihood of complications in patients undergoing elective surgery or urgent/emergent surgery. Previous studies have shown higher rates of complications following urgent/emergent surgery [4, 5, 8, 22].

However, our cohort did not show significant difference in mortality in the emergent group. Similar to mortality, this did not differ between surgeons or the 12 years included in this study period. In our study, a personal history of myocardial infarction as well as the use of a thiopurine or adalimumab prior to surgery increased the risk of Clavien–Dindo grade 3 or higher complications. These findings are similar to prior studies indicating medications, and myocardial infarction may increase the risk of postsurgical complications [15, 23–25]. Although overall complications rate remained high in both groups, majority of complications were mild and Clavien–Dindo grade 1 or 2 [22, 26, 27]. The cost associated with these complications is thought to be significantly less than those resulting from hospital readmissions and more severe Clavien–Dindo grades [22, 26, 27]. It is likely that these more minor complications are often unavoidable and focus should be on evaluating ways to reduce the risk of the grade 3 and higher complications.

With an increasing focus on reimbursements based on quality of care provided, readmission rates are being carefully evaluated [28]. In our study, readmissions were seen in 24% of cases, but they did not differ based on surgical urgency. Some readmissions are unlikely to be avoidable [29, 30]. Nagle et al. [31], however, showed that in cases of dehydration following new ostomy formation a standardized postoperative care pathway reduces the readmission rates from dehydration to 0%. However, not every risk factor like disease severity or urgency of surgery predicts readmission. Nevertheless, similar to other conditions, readmissions should ideally be reduced to under 13% at 30 days [32]. While the readmission may not be indicative of the quality of the surgical care, it may have more to do with IBD and the medications being used to treat IBD [13]. Prior studies have shown an increase in readmission rates in IBD even without surgery as well as an increase in surgical complications associated with

Table 2 Complications within 90 days

Variables	Total $N = 258$	Elective $N = 177$	Urgent/emergent $N = 81$	p Value
Any complication	121 (47)	77 (44)	44 (54)	0.109
Readmission within 30 days	61 (24)	40 (23)	21 (26)	0.636
Time to readmission, days, mean (SD)	22.9 (14.7)	19.0 (11.5)	30.5 (17.3)	0.003
Mortality at 90 days	3 (1)	2 (1)	1 (1)	1.000
Gastrointestinal	58 (23)	35 (20)	23 (28)	0.148
Infectious	35 (14)	22 (12)	13 (16)	0.438
Skin/wound (non-infection)	13 (5)	7 (4)	6 (7)	0.238
Renal/endocrine	24 (9)	17 (10)	7 (9)	1.000
Cardiovascular	3 (1)	2 (1)	1 (1)	1.000
Pulmonary	2 (1)	1 (1)	1 (1)	0.539
Hematologic	18 (7)	11 (6)	7 (9)	0.599
Neurologic	3 (1)	1 (1)	2 (3)	0.233
Clavien–Dindo grade 1	46 (18)	32 (18)	14 (17)	1.000
Clavien–Dindo grade 2	42 (16)	25 (14)	17 (21)	0.203
Clavien–Dindo grade IIIa	12 (5)	8 (5)	4 (5)	1.000
Clavien–Dindo grade IIIb	20 (8)	14 (8)	6 (7)	1.000
Clavien–Dindo grade IVa	3 (1)	1 (1)	2 (3)	0.233
Clavien–Dindo grade IVb	0	0	0	–
Grade V	3 (1)	2 (1)	1 (1)	1.000
Specific surgical complications				
DVT	13 (5)	7 (4)	6 (7)	0.238
Anastomotic leak	5 (4)	5 (4)	0 (0)	0.182
Fascial dehiscence	4 (2)	2 (1)	2 (3)	0.592
Reoperation	4 (2)	4 (2)	0 (0)	0.312
Superficial site infection	8 (3)	2 (1)	6 (7)	0.013
Fluid collection requiring just abx	3 (1)	3 (2)	0 (0)	0.554
Fluid collection requiring drainage and abx	5 (2)	4 (2)	1 (1)	1.000
Deep site infection (intra-abdominal abscess, rectal stump blowout)	6 (2)	4 (2)	2 (3)	1.000
SIRS	4 (2)	2 (1)	2 (3)	0.592
Pneumonia	1 (0)	1 (1)	0 (0)	1.000
UTI	5 (2)	4 (2)	1 (1)	1.000
ICU admission	3 (1)	2 (1)	1 (1)	1.000
Ileus	18 (7)	14 (8)	4 (5)	0.444
Bowel obstruction	14 (5)	8 (5)	6 (7)	0.379
Failure to thrive/TPN	12 (5)	6 (3)	6 (7)	0.202
Acute renal failure	2 (1)	1 (1)	1 (1)	0.530
Need for blood transfusions	13 (5)	5 (3)	8 (10)	0.028
Other	20 (8)	11 (6)	9 (11)	0.210

abx antibiotics, *TPN* total parenteral nutrition

anti-TNF medications prior to surgery [14, 33]. Additionally, similar to our study finding of myocardial infarction increasing the risk of complications, De Silva et al. [14] also noted that patients with IBD with cardiac disease are also at increased risk of surgical complications. While our study did not assess for when medications should be stopped prior to surgery or how to mitigate cardiovascular risk, further studies are warranted to determine if stoppage of IBD-specific medications prior to surgery and optimization of cardiovascular status results in reduced complications and readmissions.

Our study does have some limitations. It is a single-center study performed in a referral-based tertiary care medical center. The center has a robust inflammatory bowel disease program and colorectal surgery program. The ability to generalize these findings to the community and other practice settings is limited. Additionally, the rates of death, complications, and readmissions were all

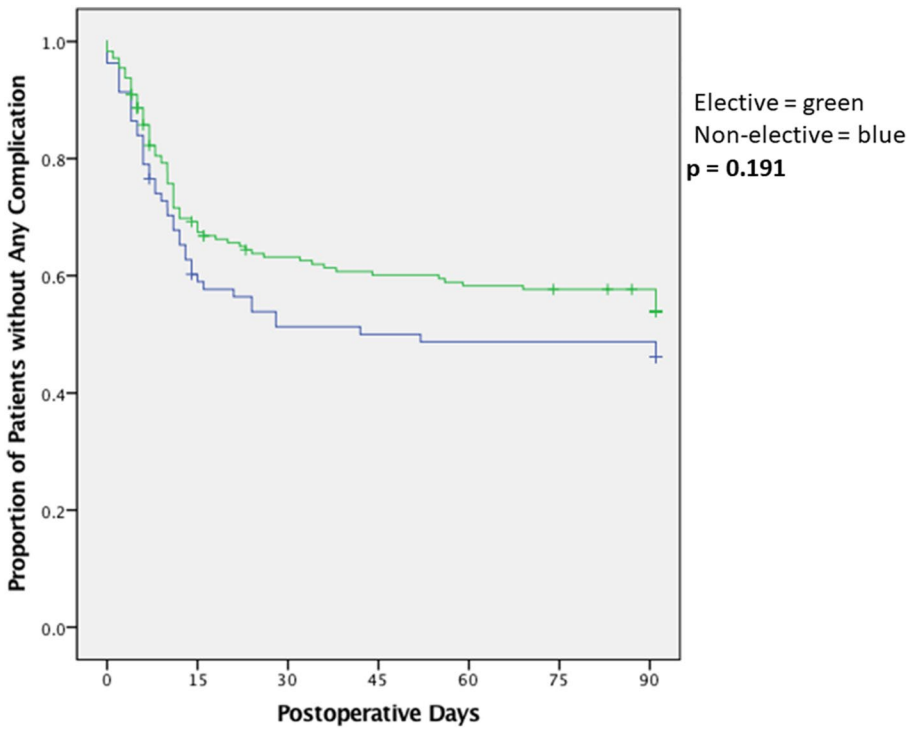

Fig. 2 Time to complication: elective versus non-elective surgery

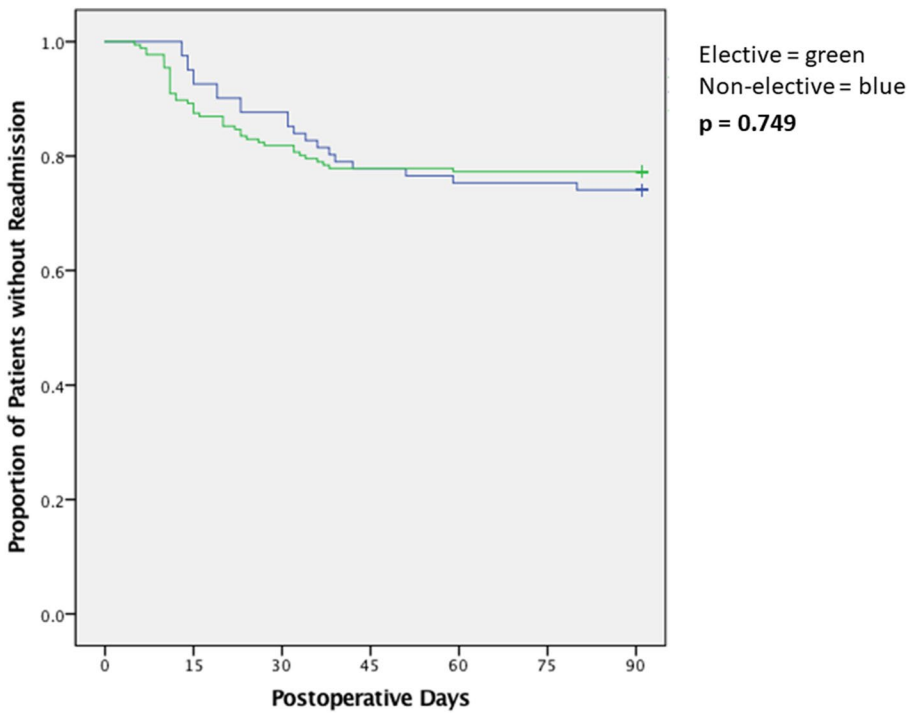

Fig. 3 Time to complication by surgical approach

dependent on accurate clinical documentation. It is possible that patients were readmitted to other centers or died without our group being informed of this. However, following a surgical procedure, patients are more likely to return to the hospital at which the surgery was performed.

Conclusion

Surgery for ulcerative colitis is not associated with any mortality at 30 days and very low mortality at 90 days.

Table 3 Multivariate model predictors of complications

Variable	Odds ratio	95% Confidence interval
MI history	6.093	1.479–25.094
Thiopurine use on admission	5.200	2.346–11.525
Adalimumab use on admission	5.516	1.622–18.761
ASA class 3 or greater	3.014	1.387–6.551

However, patients undergoing elective and urgent/emergent surgery are associated with increased rates of complications, but the majority of these complications are minor in nature. Readmissions, however, occur in nearly 25% of patients, and interventions are needed to reduce this rate. Further studies are necessary to determine how to further mitigate these complications and reduce the 90-day readmission rates following surgery for ulcerative colitis.

Author's contribution JDF and VP had full access to all of the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis. JDF, VP, T Cataldo, and KRF conceived and designed the study; JDF, MA, and T Curran acquired the data; JDF, VP, T Cataldo, T Curran, and KRF analyzed and interpreted the data; JDF and T Curran drafted the manuscript; JDF, MA, KRF, VP, and T Cataldo critically revised the manuscript for important intellectual content; T Curran performed the statistical analysis; JDF and VP supervised the study; and each author has approved the final draft of this manuscript.

Compliance with ethical standards

Conflict of interest None of the authors have any relevant conflicts of interest related to this manuscript.

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