Tech Coloproctol (2017) 21:217–223
DOI 10.1007/s10151-017-1591-2

ORIGINAL ARTICLE

Impact of preoperative steroid or immunosuppressant use on short-term outcomes following colectomy in Crohn's disease patients

N. Valizadeh[1] · A. C. A. Murray[1] · K. Suradkar[1] · A. Al-Mazrou[1] · R. P. Kiran[1]

Received: 23 August 2016 / Accepted: 28 December 2016 / Published online: 15 February 2017

Abstract
Background Evaluating the impact of steroid or immunosuppressants (SI) therapy prior to colectomy in Crohn's disease (CD) patients on postoperative septic and colectomy-specific outcomes using the American College of Surgeons (ACS)–National Surgical Quality Improvement Program (NSQIP)-targeted colectomy database.
Methods All CD patients undergoing colectomy were retrieved from the 2012–2013 NSQIP-targeted database. Thirty-day postoperative outcomes were compared for patients who were on steroids or immunosuppressants (SI) within the 30 days prior to colectomy to the others using univariable and multivariable analyses.
Results Of 2208 CD patients, 1387 (63%) were on SI. Patients in the SI group were younger, and a greater proportion underwent laparoscopic surgery ($p < 0.05$). SI use was associated with a higher rate of sepsis (7.6 vs. 5.2%), anastomotic leak (5.6 vs. 3.5%), and return to operating room (6.8 vs. 3.3%). On multivariable analysis, SI was associated with sepsis, septic shock, and anastomotic leak [odds ratio = 1.58, 95% confidence interval 1.09–2.27].
Conclusions These results suggest that SI use within 30 days of colectomy is associated with a higher rate of sepsis and septic shock and anastomotic leak in CD patients. Withholding SI prior to surgery, or the selective use of an ostomy to mitigate the consequences of a leak and hence sepsis need due consideration prior to surgery.

Keywords Crohn's disease · Steroid · Immunosuppressant · Colectomy · Postoperative outcomes

Introduction

Crohn's disease (CD) is a chronic, non-curable inflammatory disorder that requires medical and surgical therapeutic approaches for maintaining symptomatic control [1]. Steroid/immunosuppressant (SI) medications are the common options in the medical treatment of CD. Nevertheless, surgical intervention is required in up to 70% of patients to control complications like intractable hemorrhage, perforation, obstructions, abscess, dysplasia or cancer or to treat unresponsive fulminant disease [2–4]. Most of these patients are under SI therapy prior to surgery while the safety of perioperative SI use is still a cause for concern. Previous literature has conflicting reports of whether pre-op steroid use is associated with increased postoperative complications [5–8]. Several studies have shown that corticosteroid use can impair the process of wound-healing [9, 10], add to the risk of postoperative infectious complications [11], and eventually increase the length of hospital stay, cost, mortality, and morbidity rates [12, 13]. The immunosuppressive effects of corticosteroids probably account for the increased risk of postoperative infectious complications in these patients. That preoperative corticosteroid use increases the risk of complications in the postoperative period has led some clinicians to stop or reduce the dose of corticosteroid prior to surgery and even delay surgery for this reason [14]. Finding the proper balance that optimally controls disease while minimizing the

This work was presented at the 2016 American Society of Colon and Rectal Surgeons (ASCRS) Annual Meeting as a poster presentation.

✉ R. P. Kiran
rpk2118@cumc.columbia.edu

[1] Department of Colorectal Surgery, Columbia University Medical Center, Presbyterian Hospital, New York, NY 10032, USA

postoperative risk of infection and other morbidity remains a challenge.

Although previous research has identified some association between steroid use and postoperative complications after colorectal procedures in CD patients, these studies suffer from the lack of standardized definitions for both inclusion criteria and outcomes and the use of single-institution data. Some studies suggest an association between steroid use and only infectious complications while others report a higher rate of overall as well as infectious complications in steroid-taking patients [14–17]. In particular, a study that examines postoperative outcomes in colectomy patients on a national level is lacking. The American College of Surgeons (ACS)–National Surgical Quality Improvement Program (NSQIP) collects standardized data from multiple centers, more than 300 hospitals around the USA, and includes several variables, including the preoperative diagnosis, comorbidities, and preoperative steroid/immunosuppressant usage and pos-operative mortality and surgical and medical morbidities [18]. The NSQIP colectomy-targeted database adds specific variables of interest, which hence provides an opportunity to evaluate the impact of preoperative corticosteroid use on a large number of CD patients in terms of 30-day post-colectomy outcomes.

The purpose of this study is to evaluate the impact of steroid therapy prior to colectomy in CD patients on postoperative septic and colectomy-specific outcomes using the American College of Surgeons (ACS)–National Surgical Quality Improvement Program (NSQIP)-targeted colectomy database.

Materials and methods

Using the common patient identification number, the participant user file (PUF) data were linked with the NSQIP colectomy-targeted database and a 100% match was achieved. International Classification of Diseases, Ninth Revision (ICD-9) Codes were used to identify all individuals with a diagnosis of Crohn's disease (555.x) between 2012 and 2013. The American Medical Association's Current Procedural Terminology (CPT, Chicago, IL, USA) codes for colectomy (44140-47, 44150-51, 44160, 44204-08, and 44210) were used to identify patients.

Proctectomy is not included in the colectomy-targeted database and therefore was not included in our analysis. Based on ACS-NSQIP definitions, patients on steroids/immunosuppressants (SI) were those who required regular administration of oral or parenteral steroid or immunosuppressant medications (not biologic medications) within the 30 days prior to the operation. A onetime pulse, limited short course or a taper of less than 10 days duration would not qualify for inclusion as SI use. Our analysis compared SI-positive and SI-negative patients for preoperative factors, intraoperative variables, and postoperative complications.

Preoperative demographic data included age, gender, body mass index, smoking status, functional status, weight loss, anemia (HCT $< 35\%$), selected preoperative comorbidities (diabetes, pulmonary, cardiovascular, and renal disease), emergency status, preoperative mechanical bowel preparation, preoperative chemotherapy, and preoperative oral antibiotic administration. Intraoperative variables included American Society of Anesthesiologists (ASA) classification, wound classification, type of surgery, and open versus laparoscopic surgery. Primary outcomes included 30-day mortality, return to operating room, infectious complications (superficial, deep and organ space wound infections, intra-abdominal infection, pneumonia, urinary tract infection); wound dehiscence; cardiac complications (cardiac arrest and myocardial infarction); neurological sequelae (stroke and coma); renal complications (acute renal failure and progressive renal insufficiency); venous thromboembolism [deep venous thrombosis (DVT)/pulmonary embolism (PE)], anastomotic leak, prolonged postoperative ileus, sepsis and septic shock.

Categorical variables were compared for SI-positive and SI-negative groups using the Chi-squared test, while continuous variables were compared using the unpaired t test. A p value of 0.05 was considered statistically significant, and all the p values reported are two-tailed. Those variables with a p value of < 0.20 in the univariate model were selected for inclusion in the multivariate logistic regression models. Multiple logistic regression models were used to assess for predictors of selected postoperative outcomes (sepsis, septic shock, anastomotic leak) while simultaneously adjusting for other factors.

Results

Two thousand two hundred and eight CD patients who underwent colectomy between 2012 and 2013 were identified; of these, 1387 (62.8%) were on steroids/immunosuppressant medications (SI). The clinical characteristics of SI-positive and SI-negative patients are shown in Table 1. SI-positive patients were younger and less likely female. SI-negative patients were more likely to have chronic obstructive pulmonary disease (COPD) and hypertension and more likely to undergo emergency surgery. A greater proportion of patients in the SI-positive group were on antibiotics prior to surgery (28.2 vs. 26.6%, $p < .05$) and more likely to undergo laparoscopic surgery (47.9 vs. 43.5%, $p < .05$).

The postoperative infectious and non-infectious complications are shown in Table 2. There were six deaths

Table 1 Characteristics of CD patients undergoing colectomy

Demographics	Preoperative steroid or immunosuppressant use		Total	*P* value
	Yes ($n = 1387$)	No ($n = 821$)		
Median age (years)	36 (IQR)	44		.02*
Female	723 (52.1%)	462 (56.3%)	1185 (53.7%)	.06
BMI > 30 kg/m^2	254 (18.3%)	173 (21.1%)	420 (19.3%)	.11
Current smoking	332 (23.9%)	204 (24.8%)	536 (24.3%)	.63
Dyspnea	23 (1.7%)	18 (2.2%)	41 (1.9%)	.40
Dependent functional status	9 (.6%)	5 (.6%)	14 (.6%)	.91
Ventilator-dependent	2 (.1%)	1 (.1%)	3 (.1%)	.89
Chronic obstructive pulmonary disease	12 (.9%)	20 (2.4%)	32 (1.4%)	.00*
Congestive heart failure	0 (.0%)	1 (.1%)	1 (.0%)	.19
Hypertension	202 (14.6%)	157 (19.1%)	359 (16.3%)	.01*
Anemia	620 (44.7%)	357 (43.5%)	977 (44.2%)	.58
Dialysis	0 (.0%)	1 (.1%)	1 (.0%)	.19
Disseminated cancer	6 (.4%)	2 (.2%)	8 (.4%)	.47
Weight loss (>10% in last 6 months)	135 (9.7%)	74 (9.0%)	209 (9.5%)	.56
Emergency surgery	79 (5.7%)	75 (9.1%)	154 (7.0%)	.00*
Diabetes mellitus	22 (1.6%)	18 (2.2%)	40 (1.8%)	.30
Sepsis	119 (8.6%)	75 (9.1%)	187 (9.4%)	.66
Bowel preparation	555 (40.0%)	329 (40.1%)	884 (40.0%)	.80
Chemotherapy within 90 days	9 (.6%)	4 (.5%)	13 (.6%)	.63
Preoperative oral antibiotics	391 (28.2%)	196 (23.9%)	587 (26.6%)	.01*
ASA classification: 3, 4	481 (34.7%)	307 (37.5%)	788 (35.8%)	.18
Wound classification: 3, 4	558 (40.2%)	306 (37.3%)	864 (39.1%)	.17

IQR Interquartile range, *BMI* body mass index, *ASA* American Society of Anesthesiologists

* *P* value <.05 considered significant

(0.3%). There was no significant difference between the two groups in 30-day postoperative mortality. SI-positive patients had a higher risk of sepsis (7.6 vs. 5.2%, $p = .03$) and septic shock (1.1 vs. .2%, $p = .029$). Anastomotic leak was also higher (5.6 vs. 3.5%, $p = .027$) in SI-positive patients. There were no significant differences in other infectious complications [pneumonia, urinary tract infection (UTI), superficial surgical site infection (SSI), deep SSI, and organ space SSI]. There was no significant difference between the two groups in the operating time or length of total hospital stay, but SI-positive patients had a higher rate of return to the operating room. There were no significant differences between the two groups for cardiac, renal, and neurological complications, and occurrence of DVT and PE.

After adjusting for body mass index (BMI), gender, American Society of Anesthesiologists (ASA) class, preoperative smoking status, functional status, emergent or elective colectomy, coexisting anemia, diabetes and hypertension, preoperative weight loss >10%, preoperative antibiotic use, mechanical bowel preparation, and operative approach (laparoscopic vs. open), preoperative SI use was associated with a higher likelihood of postoperative complications including sepsis [odds ratio (OR) 1.49; 95% confidence interval (CI) 1.02–2.18], anastomotic leak [OR 1.59; 95% CI 1.02-2.47], and return to the operating room [OR 2.16; 95% CI 1.39–3.36]. SI therapy was not associated with any of the other complications. The results of multivariate analysis with primary outcome of sepsis, septic shock, and anastomotic leak are shown in Table 3. SI use prior to surgery was associated with higher odds of these outcomes [OR 1.58; 95% CI 1.093–2.274] along with smoking [OR 1.49; 95% CI 1.04–2.13], open approach versus laparoscopy [OR 1.49; 95% CI 1.04–2.15], and diabetes mellitus [OR 2.7; 95% CI 1.03–7.08]. Elective procedures compared to emergent surgery were associated with a lower risk of these complications [OR .40; 95% CI .25–.65].

Discussion

Although steroids and immunosuppressant use is inevitable in many situations prior to surgery in CD patients in order to induce remission, many studies suggest higher rates of infectious and non-infectious complications in these patients after surgery [17, 19–21].

Table 2 Postoperative outcomes following colectomy for CD

	Preoperative steroid or immunosuppressant use			*P* value
	Yes	No	Total	
Need for ostomy creation	557 (41.5%)	299 (36.4%)	874 (39.6%)	.02*
30-Day mortality	3 (.2%)	3 (.4%)	6 (.3%)	.51
Prolonged postoperative ileus	224 (16.1%)	136 (16.6%)	360 (16.3%)	.87
Anastomotic leak	78 (5.6%)	29 (3.5%)	107 (4.9%)	.03*
Pelvic sepsis	132 (9.5%)	60 (7.3%)	192 (8.7%)	.07
Cardiovascular complication	3 (.2%)	3 (.4%)	6 (.3%)	.51
Renal complications	13 (.9%)	8 (1.0%)	21 (1.0%)	.93
Venous thromboembolism	35 (2.5%)	14 (1.7%)	49 (2.2%)	.21
Surgical site infection	135 (9.7%)	63 (7.7%)	198 (9.0%)	.10
Wound complications	132 (9.5%)	72 (8.8%)	204 (9.2%)	.56
Ventilator >48 h	17 (1.2%)	9 (1.1%)	26 (1.2%)	.78
Wound dehiscence	12 (.9%)	7 (.9%)	19 (.9%)	.97
Superficial SSI	100 (7.2%)	56 (6.8%)	156 (7.1%)	.73
Deep incisional SSI	26 (1.9%)	10 (1.2%)	36 (1.6%)	.24
Organ space SSI	111 (8.0%)	51 (6.2%)	162 (7.3%)	.12
Sepsis	105 (7.6%)	43 (5.2%)	148 (6.7%)	.03*
Septic shock	15 (1.1%)	2 (.2%)	17 (.8%)	.03*
Pneumonia	32 (2.3%)	10 (1.2%)	42 (1.9%)	.07
Urinary tract infection	31 (2.2%)	16 (1.9%)	47 (2.1%)	.65
Bleeding requiring transfusion	123 (8.9%)	68 (8.3%)	191 (8.7%)	.64
Myocardial infarction	1 (.1%)	3 (.4%)	4 (.2%)	.12
Cardiac arrest	2 (.1%)	0 (.0%)	2 (.1%)	.28
Acute renal failure	2 (.1%)	1 (.1%)	3 (.1%)	.89
Progressive renal insufficiency	9 (.6%)	6 (.7%)	15 (.7%)	.82
Deep venous thrombosis	24 (1.7%)	11 (1.3%)	35 (1.6%)	.48
Pulmonary embolism	13 (.9%)	4 (.5%)	17 (.8%)	.24
Reoperation	95 (6.8%)	27 (3.3%)	122 (5.5%)	.00*

SSI surgical site infection

* *P* value <.05 considered significant

Table 3 Multivariable logistic regression analysis to assess predictors of postoperative sepsis, septic shock and anastomotic leak following colectomy for Crohn's disease

	Crohn's disease adjusted odds ratio	(95% CI)	*P* value
BMI >30 kg/m^2	.907	.584–1.408	.66
ASA class 1, 2 versus 3, 4	.853	.599–1.215	.38
Open approach	1.493	1.035–2.153	.03*
Prophylactic antibiotics	1.111	.890–1.386	.35
Mechanical bowel preparation	1.227	1.001–1.504	.05*
Anemia	1.039	.725–1.489	.84
Gender	.764	.543–1.073	.12
Steroid or Immunosuppressant use	1.576	1.093–2.274	.01*
Elective	.778	.689–.879	.00*
Preoperative weight loss >10%	1.292	.790–2.112	.31
Diabetes mellitus	2.698	1.029–7.078	.04*
Hypertension	.500	.283–.883	.02*
Dependent functional health status	.802	.163–3.941	.79
Smoker	1.492	1.044–2.133	.03*

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

* *P* value <.05 considered significant

Whether to stop or reduce the dose of steroid and immunosuppressant prior to surgery in these patients has long been a matter of debate, and studies that have assessed this impact in CD patients showed non-homogenous outcomes with both positive and negative results [5–7, 22, 23].

However, these studies are either small single-institutional studies or suffer from a lack of clear definitions of steroid and immunosuppressant use. This study uses a national, multicenter, clinical database with standardized data collection to evaluate the impact of preoperative SI use on postoperative outcomes following colectomy in CD patients.

The modified colectomy-specific ACS-NSQIP database which includes additional pre-op variables and outcomes contains data from more than 300 participating hospitals allows colectomy-specific outcomes to be determined. The availability of detailed patient and operative factors as well as colorectal-specific outcomes such as anastomotic leak and prolonged postoperative ileus allows on the calculation of adjusted outcomes while controlling for a number of possible confounders.

Results obtained from an analysis of the collected information in this database are likely generalizable and reproducible [18].

Our results suggest that Crohn's disease patients who are taking steroid or immunosuppressant medications (SI) prior to colectomy have significantly worse outcomes compared to those who are not taking any of these medications in a 30-day period immediately preceding the surgery.

Studies examining the impact of preoperative steroid and immunosuppressant use on post-op outcomes in Crohn's disease patients show inconsistent results [5–7, 15, 22–24], and only a few evaluate CD patients separately. These studies are mostly prospective single-institution studies with limited numbers of patients, which restricts their generalizability.

A meta-analysis of 11 of these studies evaluating the association between steroid use and postoperative outcomes in IBD patients undergoing abdominal surgery demonstrates higher overall complications as well as infectious complications among patient on steroids prior to surgery. However, the study does not distinguish the infectious or non-infectious complications by type and does not have a uniform definition for steroid use. Also it does not evaluate CD and UC patients separately and does not assess confounding factors capable of distorting the outcomes [14]. Nguyen et al. in a study of the association of preoperative SI and postoperative outcomes in IBD patients undergoing abdominal surgery using the NSQIP database found higher post-op sepsis and venous thromboembolic events (VTE) in CD patients who took steroid prior the surgery. Our results were consistent with their results showing a higher sepsis rate. However, there was no increased VTE in SI-positive patients in our study, indicating that the association that Nguyen et al. suggest in their study was probably driven by a higher burden of active disease in steroid users patients. Furthermore, having additional colectomy-specific variables, we were able to assess colectomy-specific outcomes such as anastomotic leak and postoperative ileus [17].

Our results suggest higher rates of anastomotic leak in SI users prior to colectomy both in univariate and multivariate analysis. This result was consistent with findings from a recent study of Midura et al. in which steroid use was found to be a risk factor for anastomotic leak after colectomy along with male sex, smoking history, prolonged operative time, and the open approach. They also showed that anastomotic leak was associated with higher rates of mortality, hospital stay, and reoperation [25].

It can be argued that SI use is an indicator for disease severity, and that those who have been taking SI preoperatively have had more severe refractory disease which is increasing their risk of developing post-op complication. However, in the analysis of our dataset, SI-positive patients were younger and in a generally healthier status with fewer comorbidities and fewer emergency colectomies. SI-negative patients had more comorbid conditions like COPD and HTN and were more likely to undergo emergent surgery.

To consider the effect of potential confounding factors which could influence the results and evaluate the impact of SI use on post-op infectious complications independently, we performed a multivariate analysis and found that SI use is independently associated with a higher rate of postoperative anastomotic leak, sepsis and septic shock, and return to operating room.

When adjusting for potential confounders, SI use was independently associated with increased odds of infectious complications like sepsis, septic shock, and anastomotic leak. Smoking history, diabetes mellitus, and emergent surgery were other factors associated with higher rates of sepsis and septic shock and anastomotic leak, and these results were consistent with the results reported in previous studies [25, 26]. A laparoscopic approach and hypertensive disease requiring medication were associated with a lower possibility of these outcomes.

Evaluation of non-infectious outcomes (cardiac, renal, neurologic) and infectious out comes like pneumonia, surgical site infection, and urinary tract infection showed no difference in both groups. Although our results showed no difference in the incidence of specific infectious complications like pneumonia, UTI or surgical site infection in two groups, it suggests a tendency of these infectious complications to proceed to sepsis and septic shock in the patients who are under SI treatment prior to surgery. An understanding of these potential risks prior to surgery

increases awareness in the postoperative period, enabling quick and more rigorous treatment and rescue from potential progression to sepsis following any infectious occurrence.

The results of this study are expected to help the surgeon in preoperative risk assessment and can be an important addition to decision-making strategies. Although steroids and immunosuppressant use is inevitable in many situations prior to surgery, equally, in others it may be judicious to stop them preoperatively in order to lower the rate of postoperative complications in these patients.

Even if limiting the administration of SI prior to surgery is not achievable, a prediction of risk of anastomosis-related infectious complications can give the surgeon useful information at the time of surgery when deciding whether patients may benefit from avoiding an anastomosis or the creation of a defunctioning stoma.

Although NSQIP has been shown to be an accurate and reliable database by using standardized definitions in variables and outcomes [27, 28], there were potential limitations in our study as with any other retrospective analysis. We were unable to distinguish between the effect of immunosuppressant medications and steroids since NSQIP database codes them both as one variable. A further drawback of the database is the non-availability of data relating to the concomitant use of biologic drugs. The information about the dose, name, and route of administration of steroids was also missing. The other limitation was that the analysis was limited to variables that could be captured by the data set and data beyond 30 days postoperatively were not available.

Conclusions

These results, based on an analysis of standardized perioperative data and outcomes, suggest that steroid or immunosuppressive use within 30 days of colectomy is associated with a higher rate of sepsis and septic shock and anastomosis leak in CD patients undergoing surgery. Withholding SI prior to surgery, when feasible, or the selective use of an ostomy to mitigate the consequences of a leak and hence sepsis need due consideration prior to and during surgery.

Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

Ethical approval All procedures performed in the study involving human participants were in accordance with the ethical standards of our institution and with the 1964 Helsinki declaration and its later amendments.

Informed consent For this type of study formal consent is not required.

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