Published in final edited form as:

J Gastrointest Surg. 2014 February ; 18(2): 378–384. doi:10.1007/s11605-013-2289-z.

The Impact of Laparoscopic Versus Open Approach on Reoperation Rate After Segmental Colectomy: a Propensity Analysis

Paul J. Speicher,

Department of Surgery, Duke University, Durham, NC, USA

Duke University Medical Center, Box 3443, Durham, NC 27710, USA

Brian R. Englum,

Department of Surgery, Duke University, Durham, NC, USA

Betty Jiang,

Duke University School of Medicine, Duke University, Durham, NC, USA

Ricardo Pietrobon,

Department of Surgery, Duke University, Durham, NC, USA

Christopher R. Mantyh, and

Department of Surgery, Duke University, Durham, NC, USA

Section of Colon and Rectal Surgery, Duke University, Durham, NC, USA

John Migaly

Department of Surgery, Duke University, Durham, NC, USA

Section of Colon and Rectal Surgery, Duke University, Durham, NC, USA

Paul J. Speicher: paul.speicher@duke.edu

Abstract

Background—Reoperation rate has not been well studied as a primary outcome when comparing laparoscopic with open approaches for colorectal resection. The goal of this study was to determine the impact of a laparoscopic approach on rate of reoperation after elective segmental colectomy.

Methods—The NSQIP PUF for 2005–2011 was used to retrospectively identify patients who underwent open or laparoscopic elective segmental colectomy. The primary outcome measure was 30-day reoperation rate. A multivariable logistic regression model was constructed to determine the independent effect of surgical approach on rates of unplanned reoperation. This was validated with inverse propensity score weighting.

Results—A total of 39,063 patients met the study inclusion criteria. A total of 1,702 reoperations were identified. After open approach, 5.1 % required reoperation, compared to 3.8 % in the laparoscopic group. After adjusting for confounders, open resection had 1.17-fold higher odds than laparoscopy for risk of reoperation, but this was not statistically significant ($p=0.07$).

Discussion—Using a large clinical dataset, we found that for segmental colectomy, there was not a statistically significant difference in odds of return to the operating room for laparoscopic versus open surgical approach. Reoperation is a relatively rare but costly complication and remains a potential area for quality improvement.

Keywords

Laparoscopy; Reoperation; Quality improvement; Comparative effectiveness

Introduction

Over the past 20 years, the role of laparoscopic resection has been established in the management of colorectal pathology. Compared to open procedures, laparoscopic colorectal resection has similar long-term results but with improved short-term outcomes.^{1–4} Despite this, there remains considerable variability between surgeons and institutions with respect to surgical outcomes, which are often assessed by easily quantifiable but nonspecific endpoints such as mortality rate, length of stay, and generic complication rates. Due to the inherent limitations of these, there has been mounting interest in using rates of early reoperation as a quality and outcomes indicator in colorectal surgery.^{5–8} Reoperation is a costly complication and represents a potential area for significant quality improvement in an era of increasing emphasis on reducing costs and improving patient care. To date, reoperation rate has not been studied as a primary outcome when comparing laparoscopic with open approaches for colorectal resection.

Traditional endpoints to assess surgical quality have included length of stay, in-hospital and 30-day mortality, and postoperative complications. Regrettably, these measures have significant flaws, which limit their usefulness. Postoperative mortality, while important and concrete, is often too rare to be of significant use for assessing quality of care. Similarly, morbidity endpoints are limited due to the fact that many complications are too procedure-specific to be of use across a range of procedures. Surgical site infection (SSI), which has traditionally been considered as one of the primary sources of morbidity for patients undergoing colorectal resection, nonetheless encompasses a broad range of wound infection complications, from fairly trivial to life threatening. In response to these limitations, the use of unplanned return to the operating room has gained favor as a reliable indicator of surgery-specific complications and thus surgical quality.^{5,8}

Numerous studies have included reoperation rate as a univariate secondary endpoint when comparing laparoscopic versus open approach to colorectal procedures, with variable results. Using a large administrative dataset, Burns et al. found a small increase in reoperation rate following laparoscopic colorectal resection as compared to open resection.⁶ A number of other well-designed studies have failed to demonstrate statistically significant differences in rates of reoperation when comparing laparoscopic and open approaches.^{1,3,9}

In all of these cases, reoperation rates were reported as unadjusted outcomes, limiting the utility of this measure in these studies.

Our main objective was to determine the impact of surgical approach on reoperation rates using a cohort of all segmental colon resections performed in the USA and included in the National Surgical Quality Improvement Program Participant User Files (NSQIP PUF).

Methods

Data Source

The 2005 through 2011 NSQIP Participant User Files were used for this analysis. The use of ACS NSQIP has advantages over traditional database studies, primarily stemming from the large sample sizes available. The database provides one of the largest and most current collections of clinical data available in the USA. The NSQIP database captures numerous clinically relevant perioperative variables using data from both community and academic medical centers that have been independently audited and validated. The dataset used for the current study comprises a prospectively collected cohort of colorectal resections performed between 2005 and 2011.

Study Design

Using the NSQIP PUF, we included all patients with a primary Current Procedural Terminology (CPT) code for open (44140, 44141, 44143, 44144) or laparoscopic (44204, 44205, 44206) partial, or segmental, colectomy (Fig. 1). Although NSQIP does not specifically capture cases converted from laparoscopic to open approach, we identified all patients who had a primary CPT code for open approach and secondary code for laparoscopic (or vice versa) as a presumed converted case and classified these patients into the laparoscopic group on an intent-to-treat basis. We limited our analysis to operations performed in patients with primary International Disease Classification Version-9 (ICD-9) diagnosis codes for benign or malignant neoplasms of the colon, diverticular disease, and colon polyp disease. To capture only elective cases, the following classifications and preoperative conditions were excluded: emergency cases; American Society of Anesthesiology (ASA) class 5, defined as a moribund patient who is not expected to survive without the operation; and preoperative sepsis

The primary outcome measure for our analysis was rate of early return to the operating room, defined in NSQIP as returns to the operating room within the 30-day postoperative period. Secondary outcome measures included 30-day mortality and the incidence of specific complications. Specific complications included superficial surgical site infection, deep incisional surgical site infection, organ/space surgical site infection, wound disruption, pneumonia, unplanned intubation, pulmonary embolism, ventilatory requirement greater than 48 h post-operatively, urinary tract infection, progressive renal insufficiency, acute renal failure requiring hemodialysis, stroke, coma lasting greater than 24 h, cardiac arrest, myocardial infarction, bleeding requiring transfusion within 72 h postoperatively, deep venous thrombosis, sepsis, and septic shock.

Statistical Analysis

For categorical and continuous variables, proportions and measures of central tendency were assessed, respectively. Preoperative baseline patient characteristics were compared for patients undergoing open versus laparoscopic colorectal resections using Pearson's chi-square test for categorical variables and the Wilcoxon rank sum test for continuous variables. Univariate comparison of specific postoperative complications and endpoints for the open versus laparoscopic surgical approach was performed using Pearson's chi-square tests for categorical complications and Wilcoxon rank sum tests for continuous outcomes.

To determine the independent effect of surgical approach on rates of reoperation, a nonparsimonious multiple logistic regression model was constructed to adjust for patient- and procedure-related confounding factors. In addition to surgical approach, the following predictor variables were considered for inclusion in this model: patient age, gender, body mass index, ASA classification of ≥ 3 , diabetes mellitus, tobacco use within the past year, >2 alcoholic drinks per day, dyspnea at rest or on exertion, chronic obstructive pulmonary disease, hypertension, coronary artery disease, congestive heart failure, preoperative dependence on dialysis, use of steroids within 30 days of operation for chronic medical condition, systemic chemotherapy within 30 days of operation, radiotherapy treatment for cancer in the 90 days prior to surgery, $>10\%$ loss body weight in 6 months prior to operation, bleeding disorder, case classification of contaminated or dirty, intraoperative surgical trainee participation, need for intraoperative packed red blood cell transfusion, and work RVU for each case. Because of variability in rates of utilization of a laparoscopic approach over the study timeframe (Fig. 2), year of operation was also entered into the model as a variable. The presence or absence of both an anastomosis and an ostomy was also entered into the model based on CPT code descriptions. To confirm that any observed effects were not the result of the generic nature of the 30-day return to the operating room data in NSQIP, a sensitivity analysis was then performed, looking at return to the operating room for presumed anastomotic leak. This was defined as a return to the operating room with concomitant (1) organ space surgical site infection or (2) sepsis in the absence of urinary tract infection and pneumonia, only in patients who underwent a primary procedure involving an anastomosis.

Due to the significant differences in baseline characteristics observed between the two surgical approaches, we also conducted a separate propensity-weighted analysis of the study cohort to address the possibility that there might be nonrandom, fundamental differences between patients who are selected for laparoscopic resection and those who are not. For this analysis, a generalized boosted regression model was created to estimate the likelihood of each patient being offered an open versus laparoscopic operation, and a propensity-based weight was calculated. Specifically, the variables chosen were those thought to most likely act as confounders in that they were potentially associated with a decision to offer a patient a laparoscopic approach and associated with reoperation rates.^{10–12} These included age, gender, body mass index, current smoker within 1 year of operation, dyspnea on moderate exertion or at rest, non-independent functional status, diabetes mellitus, COPD, coronary artery disease, congestive heart failure, disseminated malignancy, ASA classification greater than or equal to 3, and year of operation. Model diagnostics and balance were assessed, and

no major model assumptions were violated. The estimated propensity scores were then used to fit a generalized linear model using inverse probability weighting. The model was constructed using the same patient- and procedure-related confounding factors utilized in our primary nonparsimonious logistic regression model.

Our primary pre-specified outcome of interest was odds of reoperation within 30 days. Other outcomes were considered exploratory, and we made an affirmative decision to control for type I error at the level of the comparison. A p -value 0.05 was used to indicate statistical significance for all comparisons and analyses. Missing data were handled by complete case analysis. Statistical analyses were performed using R version 2.15.1, Vienna, Austria.

Results

Between 2005 and 2011, a total of 39,063 patients who met the study inclusion criteria were identified, of which 15,886 (40.7 %) underwent open segmental colectomy and 23,177 (59.3 %) underwent a laparoscopic approach, with an annual linear increase in percentage of cases performed laparoscopically as demonstrated in Fig. 2. The preoperative and intraoperative characteristics of the two patient groups are outlined in Table 1. There were statistically significant differences ($p < 0.05$) between groups for all baseline and intraoperative characteristics, with the exception of gender, alcohol intake, and BMI ($p = 0.07$, 0.14, and 0.24, respectively), likely as a result of a very large sample size. Differences of greater than 1 % between open and laparoscopic groups were identified for the following 11 patient characteristics: ASA class of 3 or 4 (55.3 vs. 40.8 %, $p < 0.001$), diabetes mellitus (17.5 vs. 14.9 %, $p < 0.001$), smoking status (17.6 vs. 14.5 %, $p < 0.001$), preoperative dyspnea at rest or exertion (12.9 vs. 9.6 %, $p < 0.001$), non-independent functional status (6.1 vs. 2.4 %, $p < 0.001$), COPD (6.7 vs. 4.4 %, $p < 0.001$), coronary artery disease (12.5 vs. 9.9 %, $p < 0.001$), disseminated malignancy (5.9 vs. 2.0 %, $p < 0.001$), greater than 10 % weight loss in previous 6 months (6.2 vs. 2.4 %, $p < 0.001$), bleeding disorder (4.6 vs. 2.8 %, $p < 0.001$), contaminated or dirty case classification (16.1 vs. 8.2 %, $p < 0.001$).

Unadjusted outcomes for open and laparoscopic approaches are shown in Table 2. There were statistically significant differences ($p < 0.05$) between all postoperative complications. However, similar to the differences in pre operative characteristics, many of these differences were less than 1 %. Differences of greater than 1 % between open and laparoscopic groups were identified for the following seven complications: postoperative sepsis (4.0 vs. 2.2 %, $p < 0.001$), superficial surgical site infection (8.9 vs. 5.9 %, $p < 0.001$), pneumonia (2.8 vs. 1.4 %, $p < 0.001$), unplanned intubation (2.5 vs. 1.2 %, $p < 0.001$), ventilator requirement for greater than 4 h (2.2 vs. 1.0 %, $p < 0.001$), urinary tract infection (3.4 vs. 2 %, $p < 0.001$), and postoperative bleeding (4.8 vs. 2.6 %, $p < 0.001$). A total of 1,702 reoperations were identified, representing an overall reoperation rate of 4.4 %. In the open approach group, 813 patients (5.1 %) required reoperation, compared to 889 patients (3.8 %) in the laparoscopic group (unadjusted $p < 0.001$). Overall, 30-day mortality was 1.9 % in the open approach group and 0.8 % in the laparoscopic approach group (unadjusted $p < 0.001$).

After adjusting for potential confounders using our logistic regression model, open colorectal resection did not have a statistically significant risk of reoperation compared to

laparoscopic approach (AOR 1.17, 95% CI 0.99 to 1.38, $p=0.07$). Multivariable logistic regression did, however, identify an increased risk of superficial (AOR 1.56, 95% CI 1.36 to 1.79, $p<0.001$) and deep (AOR 1.74, 95 % CI 1.23 to 2.46, $p=0.002$) surgical site infections and postoperative sepsis (AOR 1.34, 95%CI 1.1 to 1.63, $p=0.004$) in the open group compared with laparoscopic approach (Table 3). Similarly, an open approach was associated with increased odds of all-cause 30-day mortality as compared to laparoscopic approach (OR 1.49, 95 % CI 1.09 to 2.02, $p=0.01$). Lastly, we found that for only those cases with presumed anastomotic leak (return to the OR in the presence of organ space surgical site infection or sepsis after a procedure involving an anastomosis), there was again no significant difference between the laparoscopic and open groups ($p=0.17$).

Given the significant differences in baseline characteristics between patients, a clear selection bias may exist with respect to surgical approach. To account for any potential confounders that could not be addressed in our traditional regression model, a separate propensity-based analysis was conducted. Using a generalized linear regression model with inverse-probability weighting, we again failed to observe a statistically significant difference in reoperation rates between the open and laparoscopic groups (AOR 1.14, $p=0.14$). Regarding our secondary endpoint of 30-day mortality and also using propensity analysis, we demonstrated similar results to our logistic regression analysis, with increased odds of 30-day mortality seen in the open approach group (OR 1.41, 95 % CI 1.0 to 1.97, $p=0.048$).

Discussion

Laparoscopy has been established as a reliable and safe technique, with similar long-term outcomes and favorable short-term complication rates in the surgical management of colonic disease. While surgical site infection remains a significant source of morbidity and an important quality indicator in colorectal surgery, reoperation rate has not been studied as a primary outcome when comparing laparoscopic with open approaches for colorectal resection. Numerous studies have included reoperation rate as an unadjusted secondary endpoint when comparing laparoscopic versus open approach to colorectal procedures, but with inconclusive results. Using a large clinical dataset, we found no statistically significant differences in odds of reoperation after segmental colectomy between laparoscopic and open approach, although there was a trend toward a decrease risk in the laparoscopic group. One key advantage to using unplanned reoperations as an endpoint is that these are very often the result of issues related to the index procedure and therefore serve as procedure-specific indicators of quality.¹³ Over the past two decades, reoperation rate has gained significant attention, particularly when compared to the limitations of more traditional indicators such as length of stay, in-hospital and 30-day mortality, and postoperative complications.^{5,14–17}

The results of this study provide further evidence that laparoscopy is a safe and potentially superior alternative to open approach for segmental resection. Using a logistic regression model to adjust for possible confounders, we demonstrated statistically significant reduction in wound infection rates, postoperative sepsis, and death among patients undergoing a laparoscopic approach. We acknowledge that selection bias and patient attributes that are difficult to quantify may play a significant role in preoperative planning and decisions regarding surgical approach. This is particularly true in cases where laparoscopy was not

technically feasible and in cases of gross contamination where an open approach is often required. Importantly, the cohort of patients undergoing open resection was also observed to have more comorbidities than their laparoscopic counterparts, which may suggest that sicker patients are not being offered a laparoscopic approach. As these medically complex patients may in fact gain the most benefit from a minimally invasive approach, this is an area in need of further investigation.

The use of ACS NSQIP has definite advantages over traditional database studies, primarily due to the large sample sizes available. The database offers one of the largest and most current collections of clinical data available in the USA by capturing numerous clinically relevant perioperative variables. This is performed using data from both community and academic medical centers that have been independently audited and validated. Importantly, NSQIP captures patient data and outcomes using standardized definitions and does not rely on administrative data. Nonetheless, this study has limitations inherent to all retrospective studies and should be interpreted with these in mind. Most importantly, we were only able to evaluate and to adjust for variables captured and documented in the NSQIP database. Notably, CPT codes are the primary source of information related to surgical procedure and approach, and as such, while we attempted to identify converted cases as described earlier, we were unable to stratify the minimally invasive patient cohort by strict laparoscopy, hand-assisted approach, etc. Similarly, we were unable to adjust for any possible differences in surgeon and institutional volume as these data are not publicly available in the NSQIP PUF.

While Merkow et al. have demonstrated that reoperation rates as captured in NSQIP provide useful information as an indicator of quality, one potential weakness of the present study stems from the way in which returns to the operating room are documented in NSQIP.⁷ Before 2011, the only available endpoints in the PUF are returns to the operating room within 30 days for any reason. In the setting of elective segmental colectomy, however, there are very few explanations for an early return to the operating room that would not qualify as a postoperative complication. Recently, a new variable was added to the NSQIP PUF in 2011 that explicitly defined unplanned reoperations related to the index procedure. In light of this addition, we performed a subgroup analysis of the 2011 data from our study cohort and found an identical number ($n=380$) of traditional definition of generic returns to the operating room and the newly defined unplanned operations. We believe this demonstrates that, in our particular patient cohort, early return to the operating room can be assumed to represent an unplanned event.

Conclusion

Numerous studies have included reoperation rate as an unadjusted secondary endpoint when comparing laparoscopic versus open approach to colorectal procedures, with inconclusive results. We demonstrate that in patients undergoing elective segmental colectomy, laparoscopic approach has a similar risk of early return to the operating room, and a trend toward protective benefit, when compared with an open approach. Additionally, we observe small but statistically significant reductions in postoperative complications in the laparoscopic group. Rate of unplanned reoperation is known to be a valid indicator of quality and cost, and our results suggest that laparoscopic surgery is a safe, and potentially

superior, alternative to the traditional open approach in appropriately selected individuals. Reoperation is a relatively rare but important complication after colorectal surgery and remains a potential area for quality improvement and investigation in the future.

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Fig. 1. Study design for patient sample selection. *Dagger symbol* other indications were any procedures without corresponding ICD-9 code for (1) benign or malignant neoplasm of colon, (2) diverticular disease, or (3) colonic polyps. *NSQIP PUF* National Surgical Quality Improvement Program Participant Use File, *ICD-9* International Classification of Diseases —9th Version

Fig. 2.

Trends in non-emergent segmental colectomy surgical approach stratified by year as captured by ACS NSQIP

Table 1

Preoperative and intraoperative characteristics of patients undergoing segmental colectomy, stratified by surgical approach

Characteristic	Surgical approach		p-value
	Open (n=15,886)	Laparoscopic (n=23,177)	
Age	67 (56–77)	65 (55–75)	< 0.001
Female gender	8,358 (52.7 %)	11,951 (51.8 %)	0.077
BMI (kg/m ²)	27.5 (24–31.9)	27.6 (24.4–31.6)	0.235
ASA class 3 or greater	8,786 (55.3 %)	9,453 (40.8 %)	< 0.001
Diabetes mellitus	2,775 (17.5 %)	3,452 (14.9 %)	< 0.001
Tobacco smoker	2,798 (17.6 %)	3,359 (14.5 %)	< 0.001
Alcohol >2 drinks/day	548 (3.8 %)	702 (3.5 %)	0.139
Preoperative dyspnea	2,054 (12.9 %)	2,217 (9.6 %)	< 0.001
Non-independent functional status	964 (6.1 %)	563 (2.4 %)	< 0.001
Do-not-resuscitate order	164 (1.1 %)	82 (0.4 %)	< 0.001
COPD	1,062 (6.7 %)	1,027 (4.4 %)	< 0.001
Chronic steroid use	492 (3.1 %)	487 (2.1 %)	< 0.001
Coronary artery disease	1,790 (12.5 %)	1,967 (9.9 %)	< 0.001
Congestive heart failure	195 (1.2 %)	141 (0.6 %)	< 0.001
Preoperative dialysis dependence	119 (0.7 %)	83 (0.4 %)	< 0.001
Disseminated cancer	945 (5.9 %)	468 (2 %)	< 0.001
>10 % weight loss in last 6 months	981 (6.2 %)	554 (2.4 %)	< 0.001
Bleeding disorder	733 (4.6 %)	638 (2.8 %)	< 0.001
Contaminated or dirty case	2,565 (16.1 %)	1,891 (8.2 %)	< 0.001
Preoperative transfusion requirement	239 (1.5 %)	153 (0.7 %)	< 0.001
Chemotherapy in 30 days pre-op	150 (1 %)	77 (0.4 %)	< 0.001
Radiation therapy in 90 days pre-op	47 (0.3 %)	27 (0.1 %)	< 0.001
Procedure specifics			
Ostomy	2,008 (12.6 %)	275 (1.2 %)	< 0.001
Anastomosis	14,457 (91 %)	22,911 (98.9 %)	< 0.001
Resident participation in OR	8,363 (52.6 %)	11,685 (50.4 %)	< 0.001

For categorical variables, comparisons were tested with Pearson's chi-square test and Fisher's exact test, as appropriate; for continuous variables, comparisons were tested with Wilcoxon rank sum test. Continuous variables are reported as median (IQR)

* P 0.05 (considered as statistically significant)

Table 2

Unadjusted postoperative outcomes of patients undergoing segmental colectomy, stratified by surgical approach

Specific outcome/ complication	Surgical approach		p-value
	Open (n=15,886)	Laparoscopic (n=23,177)	
Early return to the OR	813 (5.1 %)	889 (3.8 %)	< 0.001
Mortality	303 (1.9 %)	176 (0.8 %)	< 0.001
Overall complication rate	4,320 (27.2 %)	3,875 (16.7 %)	< 0.001
Length of stay (days)	7 (5,11)	4 (3,6)	< 0.001
Sepsis	637 (4 %)	509 (2.2 %)	< 0.001
Septic shock	296 (1.9 %)	217 (0.9 %)	< 0.001
Superficial SSI	1,421 (8.9 %)	1,364 (5.9 %)	< 0.001
Deep SSI	241 (1.5 %)	174 (0.8 %)	< 0.001
Organ space SSI	477 (3 %)	479 (2.1 %)	< 0.001
Fascial dehiscence	255 (1.6 %)	154 (0.7 %)	< 0.001
Pneumonia	444 (2.8 %)	333 (1.4 %)	< 0.001
Reintubation	391 (2.5 %)	282 (1.2 %)	< 0.001
Prolonged ventilatory dependence	353 (2.2 %)	231 (1 %)	< 0.001
Pulmonary embolism	142 (0.9 %)	110 (0.5 %)	< 0.001
Renal insufficiency	113 (0.7 %)	96 (0.4 %)	< 0.001
Renal failure	109 (0.7 %)	76 (0.3 %)	< 0.001
Urinary tract infection	540 (3.4 %)	473 (2 %)	< 0.001
Stroke	63 (0.4 %)	54 (0.2 %)	0.005
Coma	14 (0.1 %)	6 (0 %)	0.011
Cardiac arrest	80 (0.5 %)	70 (0.3 %)	0.002
Myocardial infarction	98 (0.6 %)	95 (0.4 %)	0.005
Postoperative bleeding	755 (4.8 %)	593 (2.6 %)	< 0.001
Deep venous thrombosis	249 (1.6 %)	166 (0.7 %)	< 0.001

For categorical variables, comparisons were tested with Pearson's chi-square test or Fisher's exact test, as appropriate; for continuous variables, comparisons were tested with Wilcoxon rank sum test. Continuous variables are reported as median (IQR)

* P 0.05 (considered as statistically significant)

Table 3

Multivariable logistic regression: odds of specific outcomes following open resection as compared to laparoscopic approach

Complication	Odds ratio (95 % CI)	<i>p</i> -value
Return to the operating room within 30 days	1.17 (0.99, 1.38)	0.068
Superficial surgical site infection	1.56 (1.36, 1.79)	< 0.001
Deep incisional surgical site infection	1.74 (1.23, 2.46)	0.002
Organ space surgical site infection	1.25 (1, 1.56)	0.055
Postoperative sepsis	1.34 (1.1, 1.63)	0.004
All-cause 30-day mortality	1.49 (1.09, 2.02)	0.011
Return to the operating room for presumed leak	1.17 (0.94, 1.45)	0.166