



Original Research

Trends and outcomes in laparoscopic versus open surgery for rectal cancer from 2005 to 2016 using the ACS-NSQIP database, a retrospective cohort study



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ABSTRACT

Background: There is controversy regarding the use of laparoscopy for rectal cancer, especially after the ACOSOG Z6051 Randomized Clinical Trial determined that laparoscopy failed to meet non-inferiority compared with open surgery. With these new recommendations, the current practices for the treatment of rectal cancer across the country are unknown.

Methods: Using the ACS-NSQIP database from 2005 to 2016, resections for rectal cancer were studied. The proportion of laparoscopic versus open surgeries performed was determined by year, and 16 30-day outcomes were studied in each group. Multiple logistic regression was utilized to determine the association between laparoscopic and open technique as well as odds of outcome over time.

Results: A total of 31,795 resections were performed, 12,371 (38.9%) laparoscopically. Laparoscopy increased yearly from 9.8% in 2005 to 52.8% in 2016. All 30-day outcomes tended to favor laparoscopy with the exception of operating room time.

Conclusions: These data suggest that laparoscopic surgery has been widely adopted for treating patients with rectal cancer, and the trend continues despite the ACOSOG Z6051 recommendations suggesting that laparoscopic resection may not be best technique for resection. Stronger recommendations are needed to change current trends if laparoscopic surgery is not the appropriate treatment method for rectal cancer.

1. Background

Perioperative outcomes in patients undergoing laparoscopic compared to open surgery have been improving, and adoption of these procedures has rapidly escalated. Despite this, minimally invasive surgery in rectal cancer is more controversial now than ever before. While laparoscopy was initially limited to non-oncologic operations, it has been shown to produce equivalent oncologic outcomes as open surgery and is now a preferred technique for colon cancer resection. However, laparoscopy is technically challenging in the deep pelvis, and there is concern for adequate resection of rectal cancers.

Multiple clinical trials are ongoing to assess long-term oncologic outcomes in patients with laparoscopically-resected rectal cancers (ACOSOG, ALaCaRT, COLOR II, COREAN) [1–4]; yet, current data

examining perioperative outcomes in these patients is limited [5,6]. As there are conflicting conclusions between ongoing randomized control trials about the appropriateness of laparoscopic surgery for rectal cancers, knowledge about perioperative outcomes and trends in these outcomes over time may give surgeons more information to make clinical decisions. To address this gap, the American College of Surgeons (ACS) National Surgical Quality Improvement Program (NSQIP) database was examined to determine the prevalence of laparoscopic surgery and 30-day outcomes over a ten-year period in patients undergoing open and laparoscopic surgery for rectal cancer.

2. Methods

Institutional IRB was obtained for this retrospective cohort study,

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and the study and reporting were performed according to the agra criteria [7]. This study was also registered with clinicaltrials.gov (NCT03683446) and the Research Registry (UIN 4645). Using the American College of Surgeons National Surgical Quality Improvement Program (ACS-NSQIP) database from 2005 to 2016, colorectal procedures were identified by CPT codes and categorized to open or laparoscopic surgery (Supplemental Table). Cases were excluded if resection was not performed. Cases with primary diagnosis of rectal cancer, identified by ICD-9 code 154.1 and ICD-10 code C20, were selected. The proportion of laparoscopic surgeries performed was determined for each year. Descriptive statistics were performed for age, body mass index (BMI), and American Society of Anesthesiology (ASA) subgroups for each year to help assess complexity of cases. Cases with ASA 5 classification ($n = 8$), which is defined as a person who is moribund and not expected to survive without the operation, were excluded from analysis given this group would likely not be offered oncologic resection. Patient characteristics were compared between the two groups using two-sided t-tests for continuous data and chi-square test for categorical data. Overall and yearly means and rates were then obtained for sixteen 30-day outcomes measures. Logistic regression adjusting for the propensity score of having laparoscopic surgery was used to assess whether demographic and clinical factors are associated with higher odds of various outcomes. Covariates included year of operation, surgical technique (laparoscopic versus open), sex, age, diabetes, smoking, BMI, ASA classification, dyspnea, use of anti-hypertensive medication, chronic obstructive pulmonary disease (COPD), congestive heart failure (CHF), and steroid use. For each unique outcome, a propensity score for laparoscopic procedure (versus open surgery) was estimated using multiple logistic regression with the covariates found to be associated with the outcome on univariate analysis. Model building was performed based on the purposeful variable selection approach by Hosmer & Lemeshow [8,9]. A logistic regression model was then fit to the selected variables to determine the association between the laparoscopic procedure (or open surgery), reported as odds ratios (OR) for each outcome while adjusting for propensity score. Statistical significance was achieved for a two-tailed test with an alpha level of 0.05. All characteristics described in Table 1 were used as covariates in multiple logistic regression modeling. All statistical analyses were performed with Stata SE version 14 (College Park, TX). As robotic surgery is indicated with a modifier code and does not have its own set of CPT codes, the use of robotics is not captured in this dataset.

Table 1
Characteristics of patients undergoing laparoscopic versus open surgery.

Characteristic	Laparoscopic N = 12,335	Open N = 19,092	p-value
Male gender, N (%)	7302 (59.2)	11,793 (61.8)	< 0.001
Age, mean (SD)	60.4 (13.0)	61.9 (12.8)	< 0.001
Diabetes, N (%)	1757 (14.2)	2997 (15.7)	< 0.001
Smoking, N (%)	2117 (17.2)	3735 (19.6)	< 0.001
BMI, mean (SD)	27.6 (5.9)	28.1 (6.6)	< 0.001
ASA Classification, N (%)			< 0.001
ASA 1	308 (2.5)	350 (1.8)	
ASA 2	5836 (47.4)	7721 (40.5)	
ASA 3	5851 (47.5)	10,287 (53.9)	
ASA 4	326 (2.6)	727 (3.8)	
Dyspnea, N (%)	551 (4.5)	1357 (7.1)	< 0.001
Use of anti-hypertensive medication, N (%)	5162 (41.2)	8880 (46.5)	< 0.001
COPD, N (%)	382 (3.1)	848 (4.4)	< 0.001
CHF, N (%)	29 (0.2)	87 (0.5)	0.007
Steroid use, N (%)	286 (2.3)	456 (2.4)	0.209

ASA, American Society of Anesthesiologists; BMI, body mass index; CHF, congestive heart failure; COPD, chronic obstructive pulmonary disease, SD, standard deviation.

3. Results

A total of 31,795 resections were performed on rectal cancer patients over the cumulative twelve-year study period, 12,371 (38.9%) of which were performed laparoscopically. Over this time frame, the number of resections for rectal cancer captured by NSQIP increased from 286 in 2005 to 5249 in 2016 as more hospitals joined NSQIP (2005: 214 hospitals; 2016: 680 hospitals). The use of laparoscopy gradually increased each year, from 9.8% in 2005 to 52.8% in 2016 (Fig. 1). Laparoscopic procedures were most commonly performed in the youngest age group (18–49 years, 42.5%), patients with BMI 18.5–29.9 (BMI 18.5–24.9, 40.6%; BMI 25.0–29.9, 40.6%), and patients with ASA Class 1–2 (ASA 1, 46.8%; ASA 2, 43.0%). Over the ten-year period, a noted increase occurred in the use of laparoscopy in every age, BMI, and ASA category. From 2005 to 2016, the prevalence of laparoscopy increased from 8.7 to 55.6%, 9.4–54.0%, 11.0–51.8%, and 5.0–48.9% in groups aged 18–49, 50–64, 65–79, and 80+, respectively (Fig. 2a). Within BMI groups, the use of laparoscopy increased from 10.0% to 45.5%, 12.2–52.9%, 8.7–55.6%, 12.8–52.9%, and 3.4–49.1% in the underweight, normal weight, overweight, obese, and morbidly obese, respectively (Fig. 2b). An increase in the use of laparoscopy was also noted in patients with ASA Class 1–4 (Fig. 2c), from 20.0% to 69.7%, 10.5–58.1%, 8.7%–49.8%, and 0%–42.9%, respectively. Descriptive statistics, including gender, age, presence of diabetes, smoking, BMI, ASA classification, use of antihypertensive medication, presence of diabetes, dyspnea, COPD, CHF, and steroid use, are shown in Table 1.

All 30-day outcomes in the laparoscopic versus open groups tended to favor laparoscopy with the exception of operating room time (Table 2). In adjusted analyses, all outcomes (with the exception of operating room time) favored laparoscopic versus open resection. The difference was statistically significant in eleven outcomes: acute renal failure (OR: 0.71, $p = 0.046$); urinary tract infection (UTI) (OR: 0.78, $p < 0.001$); superficial surgical site infection (SSI) (OR: 0.51, $p < 0.001$); deep incisional SSI (OR: 0.68, $p = 0.001$); pneumonia (OR: 0.55, $p < 0.001$); ventilation for more than 48 h postoperatively (OR: 0.61, $p < 0.001$); deep vein thrombosis (OR: 0.63, $p < 0.001$); pulmonary embolism (OR: 0.50, $p < 0.001$); death (OR: 0.74, $p = 0.026$); and length of stay (laparoscopic, 6.8 days; open, 8.9 days, $p < 0.001$). Additionally, OR time was longer in the laparoscopic group even after adjusted analysis (OR > 4.5 h: 1.50, $p < 0.001$) (Table 2).

Multiple logistic regression found that six outcomes improved over time in the entire patient cohort (both laparoscopic and open patients combined). Using 2005 as a reference year, each subsequent year had 6.5% lower odds of UTI ($p < 0.001$), 8.2% lower odds of superficial SSI ($p < 0.001$), 3.3% lower odds of deep incisional SSI ($p = 0.015$), 24.0% lower odds of pneumonia ($p = 0.004$), 10.0% lower odds of ventilation for more than 48 h postoperatively ($p < 0.001$), and 0.2 less hospital days ($p < 0.001$). 3 outcomes worsened over time, with 1.9% higher odds of organ space infection per year ($p = 0.021$), 6.3% higher odds of myocardial infarction per year ($p = 0.025$), and 6.3 additional minutes of operating room time for each year past 2005 ($p < 0.001$) (Table 2).

Comparing outcomes in the entire patient cohort before and after the publication of the ACOSOG Z6051 trial results, five outcomes had statistically significant improvement in 2016 as compared to 2014, while no outcomes worsened over the two year period. Mean OR time decreased from 283.6 to 279.4 min ($p < 0.001$), mean length of stay decreased from 6.5 to 6.1 days ($p < 0.001$), incidence of postoperative acute renal failure decreased from 0.9 to 0.4% ($p = 0.024$), and superficial and deep incisional SSI decreased from 4.0 to 2.8% ($p = 0.024$) and 1.8–0.5% ($p < 0.001$), respectively.

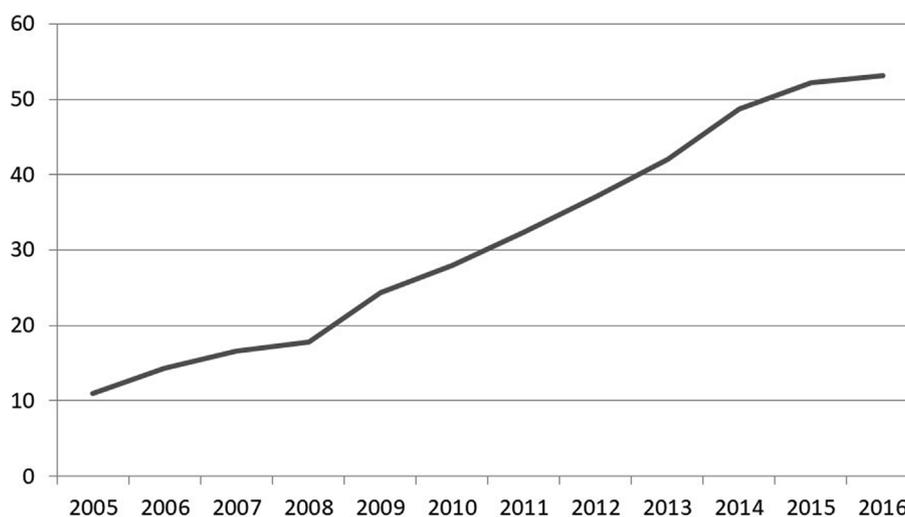


Fig. 1. Overall prevalence of laparoscopic resection for rectal cancer by year.

4. Discussion

These data suggest that minimally invasive surgery has been widely adopted for treating patients with rectal cancer, and perioperative outcomes tend to favor laparoscopic over open technique. Existing studies on perioperative outcomes in laparoscopy for rectal cancer are scarce with only four such publications currently available [5,6,10,11]. One previous study published in 2011 by Greenblatt et al., was performed in a similar fashion using the NSQIP database to analyze perioperative outcomes in 5420 patients undergoing laparoscopic versus open proctectomy for rectal cancer [5]. The study concluded that perioperative outcomes favored laparoscopy. However, specific interpretations were limited as outcomes with different magnitude of impact were combined in their analysis; for example, “respiratory complications” included both pneumonia and extended ventilator use, which have very different implications for overall recovery for the patient. Second, operating room time was not analyzed, which has been found to correlate with prolonged hospital stay, and increased complication and readmission rates [12,13]. Finally, outcomes were studied between 2005 and 2009, and since then, the use of laparoscopy has increased dramatically in all specialties. Da Luz Moreira et al., published a 1:1 case-matched study of 182 rectal cancer patients undergoing laparoscopic versus open resection and found similar 30-day mortality, 3-year disease-free survival, and local and distant recurrence rates [10]. 30-day morbidity was also found to be similar between the two groups with the exception of lower rates of SSI, faster return of bowel function postoperatively, and shorter length of hospital stay in the laparoscopic group.

Jiang et al. published a meta-analysis in 2015 based on 3678 patients [6]. They concluded that patients undergoing laparoscopic surgery had less blood loss, fewer transfusions, fewer wound infections, and shorter bowel function recovery. However, the variables studied in this meta-analysis were limited, and the current study provides a more complete analysis of perioperative outcomes by including a wider variety of outcome variables. Finally, Vargas et al., used the NSQIP database to analyze perioperative outcomes in 26,437 patients undergoing laparoscopic versus open proctectomy for both benign and malignant conditions through 2011 [11]. This analysis focused on perioperative outcomes by BMI. In this study only 47% of patients had malignancy. Perioperative outcomes determined to be superior in patients undergoing laparoscopic as opposed to open surgery. In addition to analyzing more current data, limiting the analysis to patients with primary diagnosis of rectal cancer allows us to study a more specific patient population and homogeneous disease process that will allow

better external generalizability to a specific group of patients.

The perioperative benefits of laparoscopy are not unique to colorectal surgery. In prostate cancer, when compared to retropubic radical prostatectomy, both laparoscopic and robotic assisted prostatectomy demonstrated advantages in terms of blood loss, transfusion rates, hospital stay, and rate of complications [14]. Similarly a comparison of laparotomy and laparoscopy for radical hysterectomy found that in minimally invasive techniques there was an advantage in blood loss, intraoperative injuries, and hospital stay [15]. These benefits were also consistent in other minimally invasive gynecological oncological procedures for pathologies including early stage endometrial cancer, ovarian cysts and various other pelvic masses [16]. The advances in perioperative outcomes of these minimally invasive procedures are particularly meaningful given the complex nature of operating within the pelvis.

Despite noting improved perioperative outcomes in laparoscopy, controversy still exists regarding the role of minimally invasive surgery in the treatment of rectal cancer, particularly considering long-term outcomes in the two groups.

Four large randomized controlled trials (RCT) focusing on oncologic outcomes have published conflicting conclusions, two in favor of (3, 4) and two opposed to (1, 2) laparoscopy for rectal cancer. First, in the American RCT conducted by Fleshman et al. (ACOSOG Z6051) [1], 462 patients were studied over a five year enrollment period. During their study, laparoscopic resection did not meet criteria for non-inferiority compared to open resection for clinical stage II and III rectal cancers. In gross and histologic analysis, the open proctectomy specimens tended to have higher rates of negative radial margins as well as more complete total mesorectal excision specimens, both of which have been associated with lower recurrence rates [17,18]. Similar conclusions were reached in an Australian RCT of 475 patients conducted by Stevenson et al. (ALaCaRT) [2], in which laparoscopy also failed to reach non-inferiority in rectal cancer when compared to open approaches. Although the initial predictions were that the laparoscopic method would provide improved visualization and dissection within the pelvis, this was not confirmed in the trial. The results of this trial were based upon a clear circumferential resection margins > 1 mm as well as complete mesorectal excision and both standards were superior in the open approach.

However, two RCTs concluded that laparoscopic resection was appropriate for the treatment of rectal cancer. Bonjer et al. (COLOR II) [3] conducted a multicenter European RCT of 1044 patients with a solitary adenocarcinoma of the rectum and determined that locoregional recurrence was 5% in both open and laparoscopic groups. Three year

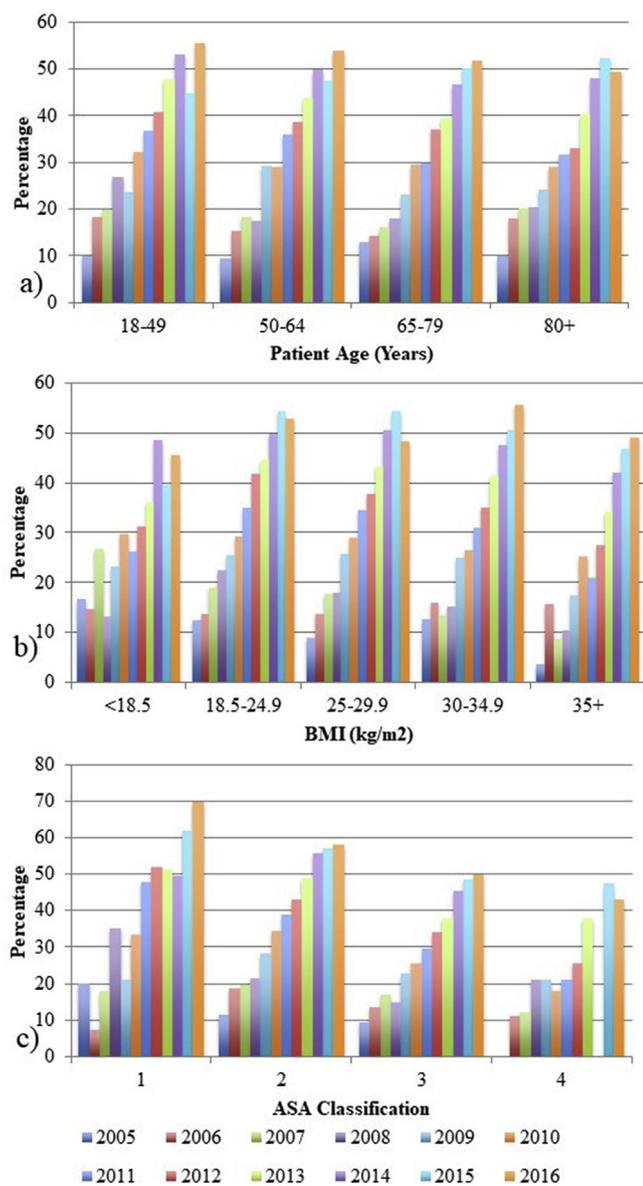


Fig. 2. Percent of Rectal Cancer Cases Performed Laparoscopically from 2005 to 2016 by a) Age b) BMI c) ASA classification.

survival rates were also similar in both groups, 86.7% in laparoscopic and 83.6% in open, indicating that laparoscopic surgery was as safe and effective as open surgery in rectal cancers. A similar trial conducted in Korea by Jeong et al. (COREAN) [4] aimed to compare short-term and long-term outcomes in resection of cT3N0-2M0 mid or low rectal cancers in open (n = 170) and laparoscopic (n = 170) surgeries. The study found that in combination with neoadjuvant chemoradiotherapy, laparoscopic procedures were not inferior to open in terms of 3-year disease-free survival (79.2% vs. 72.5%), overall survival (91.7% vs. 90.4%), and local recurrence (2.6% versus 4.9%), concluding that laparoscopic resection could be justified in rectal cancer. The results of these international studies indicate that laparoscopic resection may be a viable consideration in rectal cancer.

Many considerations may affect the future of surgical treatment for rectal cancer. First, perioperative outcomes as well as long-term outcomes are both important considerations when determining the treatment of choice for a patient; if the patient does not do well in the perioperative period, long-term oncologic outcomes are irrelevant. Though major studies rejected non-inferiority of laparoscopic surgery in rectal cancer due to concerns for adequate oncologic resection, the

Table 2
30-Day outcomes in laparoscopic (lap) versus open surgery groups.

Outcome	Lap, n (%)	Open, n (%)	P-value
	n = 12,335	n = 19,092	
Death	83 (0.7%)	223 (1.2%)	< 0.001
Cardiac Arrest Requiring CPR	35 (0.3%)	82 (0.4%)	0.068
Cerebrovascular Accident	16 (0.1%)	53 (2.8%)	0.006
Myocardial Infarction	57 (0.5%)	127 (0.7%)	0.106
Pulmonary Embolism	50 (0.4%)	145 (0.8%)	< 0.001
Deep Vein Thrombosis	98 (0.8%)	262 (1.4%)	< 0.001
Pneumonia	147 (1.2%)	465 (2.4%)	< 0.001
Ventilator > 48 Hours	86 (0.7%)	309 (1.6%)	< 0.001
Superficial SSI	483 (3.9%)	1692 (8.9%)	< 0.001
Deep Incisional SSI	177 (1.4%)	458 (2.4%)	< 0.001
Organ Space Infection	749 (6.1%)	1250 (6.5%)	0.109
Renal Insufficiency	146 (1.1%)	283 (1.5%)	0.068
Acute Renal Failure	52 (0.4%)	136 (0.7%)	0.002
Urinary Tract Infection	383 (3.1%)	881 (4.6%)	< 0.001
Length of Hospital Stay Days ^a (SD)	6.5 (7.1)	8.9 (8.5)	< 0.001
Operating Room Time in Minutes ^b (SD)	276.1 (115.7)	246.8 (127.9)	< 0.001

CPR, cardiopulmonary resuscitation; SSI, surgical site infection; SD, standard deviation.

^a Length of stay > 7days.

^b Operating room time > 270 min.

Table 3
Adjusted odds ratios of 30-day outcomes in laparoscopic (lap) versus open surgery groups and over time.

Outcome	OR ^a lap	p-value	OR ^a year	p-value
Death	0.74	0.026	0.98	0.206
Cardiac Arrest Requiring CPR	0.79	0.262	1.01	0.823
Cerebrovascular Accident	0.57	0.054	0.96	0.261
Myocardial Infarction	0.76	0.093	1.06	0.025
Pulmonary Embolism	0.50	< 0.001	1.04	0.160
Deep Vein Thrombosis	0.63	< 0.001	0.98	0.269
Pneumonia	0.55	< 0.001	0.76	0.004
Ventilator > 48 Hours	0.61	< 0.001	0.90	< 0.001
Superficial SSI	0.51	< 0.001	0.92	< 0.001
Deep Incisional SSI	0.68	< 0.001	0.97	< 0.001
Organ Space Infection	0.91	0.053	1.02	0.021
Renal Insufficiency	0.83	0.090	1.03	0.083
Acute Renal Failure	0.71	0.046	0.97	0.167
Urinary Tract Infection	0.78	< 0.001	0.94	< 0.001
Length of Hospital Stay ^b	0.43	< 0.001	0.96	< 0.001
Operating Room Time ^c	1.50	< 0.001	1.07	< 0.001

OR, odds ratio; CPR, cardiopulmonary resuscitation; SSI, surgical site infection.

^a After adjusting for covariates and propensity score in logistic regression.

^b Length of stay > 7days.

^c Operating room time > 270 min.

current study suggests that perioperative course is significantly improved in patients undergoing laparoscopic compared to open surgery. Interestingly, even after the publication of these trials' results, the rate of laparoscopy has continued to increase.

Given potential problems with adequate oncologic resection with laparoscopy but improved perioperative outcomes, robotic surgery may have an important role in pelvic surgery and specifically in the treatment of rectal cancer in the future. Specifically, due to the technical difficulty of laparoscopic surgery in the pelvis it has been hypothesized that robotic assisted surgery could enhance visibility and dexterity [19]. Several studies have analyzed the safety and efficacy of robotic assisted total mesorectal excision (RTME) [20–22]. Unfortunately, the current study was unable to assess robotic surgery due to limitations of the database. A large scale RCT is still needed to compare long-term oncological outcomes between the two methods.

As the NSQIP database only followed patients for 30 days post-operatively, the current study is unable to analyze long-term or oncologic

outcomes. Furthermore, as this is a retrospective cohort study, additional limitations include possible unequal baseline characteristics of the patients as well as unequal training and capability of surgeons that were not accounted for in adjusted analyses. However, the multiple logistic regression analysis employed in the current study may reduce some of the bias introduced by the retrospective nature of this data.

More studies are needed to further evaluate trends in the treatment of rectal cancer, particularly from 2016 onwards, given mixed results of ACOSOG Z6051, ALaCart, COLOR II, and the COREAN randomized controlled trials studying long-term outcomes in rectal cancer patients. Oncologic outcomes must be considered when determining the best treatment options of patients with rectal cancer. However, improved perioperative outcomes with minimally invasive technique could be a barrier for some surgeons to return to open technique, and perioperative outcomes will continue to be an important consideration along with long-term outcomes.

5. Conclusions

These data suggest that minimally invasive surgery has been widely adopted for treating patients with rectal cancer, and there continues to be an increase in the use of laparoscopy in the surgical treatment of rectal cancer despite recommendations suggesting that laparoscopic resection failed to meet the criterion for non-inferiority for pathologic outcomes compared to open resection. Furthermore, perioperative outcomes tend to favor laparoscopic over open technique, which could be a barrier for some surgeons to return to open technique. Further recommendations are needed to change current trends if laparoscopic surgery is not the preferred treatment method for rectal cancer. Additionally, long-term oncologic outcomes need to be better evaluated in patients who receiving laparoscopic surgery for treatment of rectal cancer.

Provenance and peer review

Not commissioned, externally peer-reviewed.

Data statement

Data for the current study will not be shared as it is owned by the American College of Surgeons. Data may be requested at <https://www.facs.org/quality-programs/acs-nsqip/participant-use/puf-form>.

Ethical approval

Houston Methodist Hospital IRB #Pro00014677.

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Author contribution

Data collection and analysis: CHD, LWM, HH, JMY, MVC.
Drafting of manuscript: CHD, TG, HH, MVC.
Critical edits: CHD, TG, LWM, XLD, HH, JMY, HRB, MVC.

Conflicts of interest

None.

Research registry number

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Guarantor

CHD, MVC.

CRedit authorship contribution statement

Catherine H. Davis: Conceptualization, Data curation, Formal analysis, Investigation, Project administration, Software, Supervision, Writing - original draft, Writing - review & editing. **Tanmay Gaglani:** Data curation, Writing - original draft. **Linda W. Moore:** Conceptualization, Data curation, Writing - review & editing. **Xianglin L. Du:** Conceptualization, Investigation, Writing - review & editing. **Hyunsoo Hwang:** Formal analysis, Writing - original draft. **Jose-Miguel Yamal:** Formal analysis, Writing - review & editing. **H. Randolph Bailey:** Supervision, Writing - review & editing. **Marianne V. Cusick:** Conceptualization, Data curation, Investigation, Project administration, Supervision, Writing - original draft, Writing - review & editing.

Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.ijso.2019.02.006>.

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