The American Journal of Surgery 220 (2020) 401–407

Contents lists available at ScienceDirect

The American Journal of Surgery

journal homepage: www.americanjournalofsurgery.com

A NSQIP analysis of trends in surgical outcomes for rectal cancer: What can we improve upon?

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ARTICLE INFO

Article history:
Received 7 August 2019
Received in revised form
1 December 2019
Accepted 4 January 2020

Keywords:
NSQIP
Rectal cancer
Surgical outcomes

ABSTRACT

Background: There is significant variation in rectal cancer outcomes in the USA, and reported outcomes have been inferior to those in other countries. In recognition of this fact, the American College of Surgeons (ACS) recently launched the Commission on Cancer (CoC) National Accreditation Program for Rectal Cancer (NAPRC) in an effort to further optimize rectal cancer care. Large surgical databases will play an important role in tracking surgical and oncologic outcomes. Our study sought to explore the trends in surgical outcomes over the decade prior to the NAPRC using a large national database.

Methods: The ACS National Surgical Quality Improvement Program (NSQIP) database from 2005 to 2017 was used to select colorectal cancer cases which were divided into abdominal-colonic (AC) and pelvic-rectal (PR) cohorts based upon the operation performed. Outcomes of interest were occurrence of any major surgical complication, mortality within 30 days of procedure, and postoperative length of stay (LOS). Chi-square and two sample t-tests were used to evaluate association between various risk factors and outcomes. Modified Poisson regression was used to compare and estimate the unadjusted and adjusted effect of procedure type on the outcomes. STATA 15.1 was used for analysis and statistical significance was set at 0.05.

Results: A total of 34,159 patients were analyzed. AC cases constituted 50.7% of the overall cohort. The two groups were relatively similar in demographic distribution, but the PR patients had higher rates of hypoalbuminemia and were sicker (ASA class 3 or greater). Rates of non-sphincter preserving operations ranged from 30 to 34%. Higher complication rates in the PR cohort were mainly infectious and surgical site complications, while rates of deep vein thrombosis and pulmonary embolism were similar between the two cohorts. On bivariate analysis, rates of mortality were similar between the two groups (AC: 1.02% vs PR: 0.91%, $p = 0.395$), while PR patients were found to be 1.36 times (95% CI: 1.32–1.41) more likely to have major complications and 1.40 times (95% CI: 1.35–1.44) more likely to have an extended LOS as compared to the AC patients. After multivariable analysis, PR patients continued to have a higher likelihood of major complications (IRR: 1.31, 95% CI 1.25–1.36) and extended LOS (IRR: 1.38, 95% CI: 1.33–1.43). 10-year trends showed a significant reduction in the percentage of patients with prolonged lengths of hospitalization as well as a reduction of nearly 20% in the mean LOS, but without improvement in morbidity or mortality.

Conclusions: Patients undergoing PR operations were more likely to have had major complications than were patients who underwent AC procedures; unfortunately no improvement in the rate of these complications or in mortality occurred. Perhaps the significant reduction in LOS is due in part to an increased prevalence of minimally invasive surgery and/or enhanced recovery protocols. Data were found to be lacking within NSQIP for several important variables including key oncologic data, stratification by surgical volume, and patient geographic location. We anticipate that the NAPRC should help improve PR surgical and oncologic outcomes including decreasing morbidity and mortality rates during the next decade.

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https://doi.org/10.1016/j.amjsurg.2020.01.004
0002-9610/

Introduction

The incidence of rectal cancer is increasing annually in the United States and is expected to surpass 44,000 new cases in 2019.[1] The current management of rectal cancer is now more varied and complex because of new approaches in multimodality treatment and surgical techniques.[2,3] Despite recent advances in new chemotherapeutic regimens, approximately 8500 patients will die of this disease. Compared to European countries, the United States has been lacking in practice-based models for many types of cancer treatment and outcomes including rectal cancer.[4,5] Determining factors that affect surgical and oncologic outcomes are crucial to improving care for patients with rectal cancer.

There is significant variation in rectal cancer outcomes in the USA, and reported outcomes have been inferior to those in other countries. The reasons for this are multifactorial and include patients being treated at lower-volume centers by surgeons with inadequate or outdated training experience.[6,7] This has resulted in widely variable colostomy rates, postoperative and oncologic outcomes, and mortality.[8,9] In recognition of this fact, the American College of Surgeons (ACS) recently launched the Commission on Cancer (CoC) National Accreditation Program for Rectal Cancer (NAPRC) in an effort to further optimize rectal cancer care.[10,11] Large surgical databases will play an important role in tracking surgical and oncologic outcomes.

Our hypothesis was that morbidity and mortality related to the surgical treatment of rectal cancer would have declined over the previous decade as a result of advances in surgical techniques and perioperative care. Therefore, the purpose of our study was to explore the trends in complication rates and surgical outcomes over the previous decade using a large national database. Identifying these trends and factors could help improve patient outcomes, decrease health care costs, and help to focus future efforts to improve rectal cancer care.

Materials and methods

This was an Institutional Review Board approved, retrospective cohort study using the ACS NSQIP database. NSQIP is a nationally validated, risk-adjusted, outcomes-based program to measure and improve the quality of surgical care. The NSQIP database is comprised of over 150 variables, including patient demographics, preoperative risk factors, intra-operative variables, and 30-day postoperative morbidity and mortality outcomes for a sample of patients undergoing major surgical procedures at participating hospitals.[12] A surgical clinical reviewer records de-identified patient demographic information, comorbidities, laboratory results, intra-operative details, postoperative occurrences, and 30-day mortality, and hospital readmission.[13]

The study was limited to patients from 2006 to 2017 with a preoperative diagnosis of rectal cancer. Current procedural terminology (CPT) codes and procedures are listed in Table 1. Both laparoscopic and open cases were included. Because NSQIP does not differentiate tumor height (upper, middle, or lower rectum), patients were divided into two cohorts based on CPT coding: abdominal-colonic (AC) and pelvic-rectal (PR).

Pre-operative patient demographics considered as potential confounders included age, gender, body mass index (BMI), American Society of Anesthesiologists (ASA) risk class, smoking status, functional status, presence of sepsis, >10% loss body weight over previous 6 months, steroid dependence, and preoperative blood transfusion >1 unit. Comorbidities of interest included chronic obstructive pulmonary disease (COPD), dyspnea, ascites, hypertension, congestive heart failure (CHF), diabetes, end stage renal disease, history of bleeding disorder, insulin-dependent diabetes, and smoking status. Operative factors included surgical approach (laparoscopic versus open) and operative time.

Outcomes of interest included major postoperative complications, mortality, and extended hospital length of stay (HLOS) defined by hospital stay greater than seven days. Major post-operative complications included superficial surgical site infection (SSI), deep SSI, organ space SSI, wound dehiscence, pneumonia, post-operative re-intubation, prolonged mechanical ventilation postoperatively, myocardial infarction, cerebrovascular accident (CVA), venous thromboembolism (VTE), acute renal failure (ARF), urinary tract infection (UTI), post-operative bleeding requiring blood transfusion, and presence of septic shock.

Statistical analysis

Patient demographics, comorbidities, and major post-operative complications were compared using chi-square or *t*-tests, as appropriate. Unadjusted and multivariable adjusted analysis was performed in order to control for patient factors and comorbidities. Data were also analyzed by year in order to determine long-term trends in surgical outcomes. Analysis was performed for patients with complete data for all variables of interest. Missing data comprised less than 5% of the original cohort and was imputed. Modified Poisson regression and robust standard errors were used to estimate the risk ratios associated with various risk factors for mortality and morbidity.[14] HLOS was log transformed and calculated as the ratio of mean difference, and the effect of various risk factors was assessed using linear regression.[15] Variables significant at 0.10 level of significance were considered for adjustment in the multivariable adjusted analysis. All statistical analyses were performed using Stata software, version 14.0 (Stata Corp), using a *p*-value of 0.05 for 2-tailed tests as a cutoff for statistical significance.

Results

Demographics and operative categories

The demographic data for the two groups is presented in Table 2. A total of 34,159 patients with rectal cancer were queried from 2006 to 2017. 17,315 (50.7%) of these patients underwent AC procedures and 16,844 (49.3%) underwent PR procedures. There was a slightly higher percentage of women who underwent AC procedures (40% vs. 38%, Table 2, $p < 0.001$), and conversely more men underwent PR procedures (60% vs. 62%, $p < 0.001$). The age distribution was relatively similar between the AC and PR groups (mean age; 60.5 vs. 61.5). The ethnic distribution was also relatively similar between the two groups. The AC group had significantly more patients classified as ASA class 1 or 2 (48% vs. 42%), while more patients with an ASA 3 underwent PR procedures (49% vs. 54%). The AC group had more patients with a BMI >30 (32% vs. 30%) and fewer patients with a BMI <30 (68% vs. 70%). The AC group had fewer patients with malnutrition as evidenced by a higher proportion with albumin >3.5 (87% vs. 47%) and a lower proportion with albumin <3.5 (13% vs. 53%). AC patients were also less likely to be current smokers (17% vs. 19%) and have significant preoperative weight loss (4% vs. 6%). The two cohorts had fairly similar rates of other comorbidities such as hypertension (44% vs. 45%), dyspnea (5% vs. 6%), COPD) (4% vs. 4%), congestive heart failure (CHF) (0.4% vs. 0.4%), bleeding disorder (2% vs. 3%), significant anemia (5% vs. 6%), chronic kidney disease (11% vs. 11%), diabetes (5% vs. 5%), and chronic steroid use (2% vs. 3%).

Table 1
Intestinal surgery current procedural terminology codes.

	ICD-9, ICD-10 Codes		
	154.1 C20		
	Total Cases	N 34,159	% total 100.00
	Abdominal Colonic Cases	17,315	50.69
44206	Laparoscopy, surgical; colectomy, partial, with end colostomy and closure of distal segment (Hartmann type procedure)	297	0.87
44207	Laparoscopy, surgical; colectomy, partial, with anastomosis, with coloproctostomy (low pelvic anastomosis)	6782	19.85
44208	Laparoscopy, surgical; colectomy, partial, with anastomosis, with coloproctostomy (low pelvic anastomosis) with colostomy	1842	5.39
44145	Colectomy, partial; with coloproctostomy (low pelvic anastomosis)	5240	15.34
44146	Colectomy, partial; with coloproctostomy (low pelvic anastomosis), with colostomy	2151	6.30
44147	Colectomy, partial; abdominal and transanal approach	222	0.65
44150	Colectomy, total, abdominal, without proctectomy; with ileostomy or ileoproctostomy	141	0.41
44210	Laparoscopy, surgical; colectomy, total, abdominal, without proctectomy, with ileostomy or ileoproctostomy	115	0.34
44204	Laparoscopy, surgical; colectomy, partial, with anastomosis	525	1.54
	Pelvic Rectal Cases	16,844	49.31
45110	Proctectomy; complete, combined abdominoperineal, with colostomy	6266	18.34
44211	Laparoscopy, surgical; colectomy, total, abdominal, with proctectomy, with ileoanal anastomosis, creation of ileal reservoir (S or J), with loop ileostomy, with or without rectal mucosectomy	251	0.73
44212	Laparoscopy, surgical; colectomy, total, abdominal, with proctectomy, with ileostomy	282	0.83
44155	Colectomy, total, abdominal, with proctectomy; with ileostomy	448	1.31
44156	Colectomy, total, abdominal, with proctectomy; with continent ileostomy	14	0.04
45111	Proctectomy; partial resection of rectum, transabdominal approach	1445	4.23
45114	Proctectomy, partial, with anastomosis; abdominal and transsacral approach	115	0.34
45123	Proctectomy, partial, without anastomosis, perineal approach	153	0.45
45119	Proctectomy, combined abdominoperineal pull-through procedure (eg, colo-anal anastomosis), with creation of colonic reservoir (eg, J-pouch), with or without proximal diverting ostomy	1229	3.60
45112	Proctectomy, combined abdominoperineal, pull-through procedure (eg, colo-anal anastomosis)	1054	3.09
45113	Proctectomy, partial, with rectal mucosectomy, ileoanal anastomosis, creation of ileal reservoir (S or J), with or without loop ileostomy	269	0.79
45395	Laparoscopy, surgical; proctectomy, complete, combined abdominoperineal, with colostomy	3405	9.97
45397	Laparoscopy, surgical; proctectomy, combined abdominoperineal pull-through procedure (eg, colo-anal anastomosis), with creation of colonic reservoir (eg, J-pouch), with diverting enterostomy, when performed	1913	5.60

Complications

The analysis of complications after unadjusted analysis (Table 2) revealed significantly less superficial and deep SSIs in the AC cohort (4.8% vs. 8.1%, 0.9% vs. 2.8%, $p < 0.001$). There were also significantly lower rates of wound dehiscence (0.9% vs. 2.2%, $p < 0.001$), UTIs (3.3% vs. 4.6%, $p < 0.001$), post-operative transfusion requirement (5.9% vs. 11.4%, $p < 0.001$), pneumonia (1.7% vs. 2%, $p = 0.03$), and post-operative sepsis (3.6% vs. 4.0%, $p < 0.001$) in the AC cohort. There was a slightly higher percentage of deep space SSI in the AC cohort (7.0% vs. 6.1%, $p < 0.001$). There were no differences in rates of reintubation, pulmonary embolism, ventilator requirement of greater than 48 h, acute renal failure, CVA with neurologic deficit, cardiac arrest requiring CPR, myocardial infarction, deep vein thromobosis (DVT) or septic shock.

Surgical outcomes

Risk ratios for overall mortality, overall morbidity, and extended HLOS were calculated using unadjusted and multivariable adjusted analysis (Table 3). Mortality rates were similar between the two groups (1.0% vs, 0.9%, $p = 0.40$, Table 3). Overall morbidity was significantly lower in the AC cohort (23.1% vs. 31.5%, $p < 0.001$, Table 3). Rates of extended HLOS were also significantly lower in the AC cohort (26.2% vs. 36.5%, $p < 0.001$, Table 3). After unadjusted analysis, patients undergoing PR procedures were found to be more likely to have major complications (RR = 1.36; 95% CI, 1.32–1.41, Fig. 1) and have extended hospital LOS (RR = 1.40; 95% CI, 1.35–1.44, Fig. 1) compared to the AC patients. Even after multivariable adjusted analysis, PR patients continued to have higher rates of major complications (RR = 1.31; 95% CI, 1.25–1.36, Fig. 1) and extended hospital LOS (RR = 1.38; 95% CI, 1.33–1.43, Fig. 1) compared to the AC patients.

Surgical outcomes were also trended by year (Fig. 2). Mortality ranged from 0.4% to 1.9% between the two groups but was not significantly different between 2006 and 2017. Overall morbidity ranged from 19.7% to 28.9% in the AC cohort and from 26.5% to 37.4% in the PR cohort, which was also not significantly different from 2006 to 2017. However, in the AC cohort, mean HLOS improved from 7.8 days in 2006 to 6.3 days in 2017, and in the PR cohort improved from 8.5 days in 2006 to 7.3 days in 2017. Additionally, rates of extended HLOS declined in the AC cohort from 34.9% in 2006 to 23.2% in 2017, and in the PR cohort improved from 43.1% in 2006 to 29.4% in 2017.

Discussion

Rectal cancer care has undergone significant changes within the past four decades, and many countries throughout the world have been developing programs to improve patient outcomes. Sweden has developed new standards for rectal cancer care, including implementing high-volume specialists and multidisciplinary tumor board meetings, and this has resulted in decreased local recurrence and improved overall survival.[16] Other European countries have followed this pattern with similar projects that have led to standard implementation, standardized treatment, and resulted in improved outcomes.[17–19] The United States launched the NAPRC in 2017 in order to improve the care of rectal cancer patients. The aim of this study was to describe the surgical outcomes of rectal cancer during the previous decade using a large nationwide database as a baseline prior to the inception of the performance measures of the NAPRC.

The results of this analysis indicate that patients with

Table 2
Demographic data.

	Abdominal-Colonic n (%)	Pelvic-Rectal n (%)	*p*-value
Total	17,315	16,844	
Gender			
Female	6930 (40)	6423 (38)	<0.001
Male	10,373 (60)	10,415 (62)	<0.001
Age			
18–30 y	136 (1)	173 (1)	
31–40 y	738 (4)	746 (5)	
41–50 y	2726 (16)	2480 (15)	
51–60 y	5131 (30)	4401 (26)	
61–70 y	4628 (27)	4572 (27)	
71–90 y	3830 (22)	4340 (26)	
Race			
White	12,323 (71)	12,086 (72)	<0.001
Black	1009 (6)	1173 (7)	0.06
Asian	777 (4)	643 (4)	0.30
Hispanic	564 (3)	636 (3)	0.35
Other	96 (1)	155 (1)	0.37
Unknown	2546 (15)	2151 (13)	<0.001
ASA Class			
1 to 2	8230 (48)	7196 (43)	<0.001
3	8544 (49)	9026 (54)	<0.001
4 to 5	518 (3)	599 (3)	0.09
BMI			
<30	11,650 (68)	11,647 (70)	<0.001
>30	5505 (32)	5031 (30)	<0.001
Current smoker	2926 (17)	3261 (19)	<0.001
Dialysis	35 (0.2)	44 (0.3)	<0.001
Ascites	811 (3)	120 (4)	0.06
Hypertension	7545 (44)	7562 (45)	0.01
Insulin use	755 (5)	762 (5)	0.24
COPD	607 (4)	642 (4)	0.13
Congestive heart failure	68 (0.4)	67 (0.4)	0.94
Dyspnea	875 (5)	963 (6)	<0.001
Chronic steroid use	339 (2)	454 (3)	<0.001
Bleeding disorder	406 (2)	446 (3)	0.07
Preoperative weight loss	706 (4)	1065 (6)	<0.001
	Abdominal-Colonic n (%)	**Pelvic-Rectal n (%)**	***p*-value**
Hematocrit			
<31	790 (5)	923 (6)	<0.001
31-45	14,626 (88)	14,376 (88)	0.10
>45	2211 (8)	107 (3)	<0.001
Creatinine			
<1.19	14,604 (89)	14,175 (89)	0.07
>1.19	1758 (11)	1819 (11)	0.15
WBC			
<4	2442 (15)	2460 (15)	0.18
4-11	13,745 (83)	13,291 (82)	0.07
>11	437 (3)	465 (3)	0.23
Albumin			
≥3.5	10,834 (87)	10,017 (47)	<0.001
<3.5	1558 (13)	1931 (53)	<0.001
Metastatic Cancer	1432 (8)	1649 (10)	<0.001
Chemotherapy <30 days			
Yes	539 (6)	720 (7)	<0.001
Unknown	5138 (55)	5318 (52)	<0.001
Radiotherapy <30 days			
Yes	1497 (16)	2029 (20)	<0.001
Unknown	5163 (55)	5338 (52)	<0.001

BMI=body mass index; ASA=American Society of Anesthesiologists; COPD=chronic obstructive pulmonary disease; WBC=white blood cells

malignancy undergoing PR operations are more likely to have major complications than patients undergoing AC procedures and despite practice changes over the past decade, there have been no significant improvements in 30-day morbidity or mortality. Significant improvements in post-operative length of stay were achieved which were not associated with increased morbidity or mortality, and are likely related to the increased incidence of enhanced recovery programs and minimally invasive surgery. We feel these observations are important because they highlight a need for more focused national level datasets that report rectal cancer specific metrics previously proven to help reduce morbidity/mortality.[20–22]

One of the goals of the NAPRC is that dedicated program coordination will lead to improvements across multiple disciplines including pathology, radiology and oncology. Some of the appealing rationale to the creation of the NAPRC was the evidence from multiple European countries of improvement in short term morbidity as well as long term oncologic outcomes by the creation of similar antecedent programs. Preliminary single institution studies have shown that pre- and post-implementation of NAPRC accreditation has led to significant improvements in reporting of important quality metrics. Numerous studies in the United States

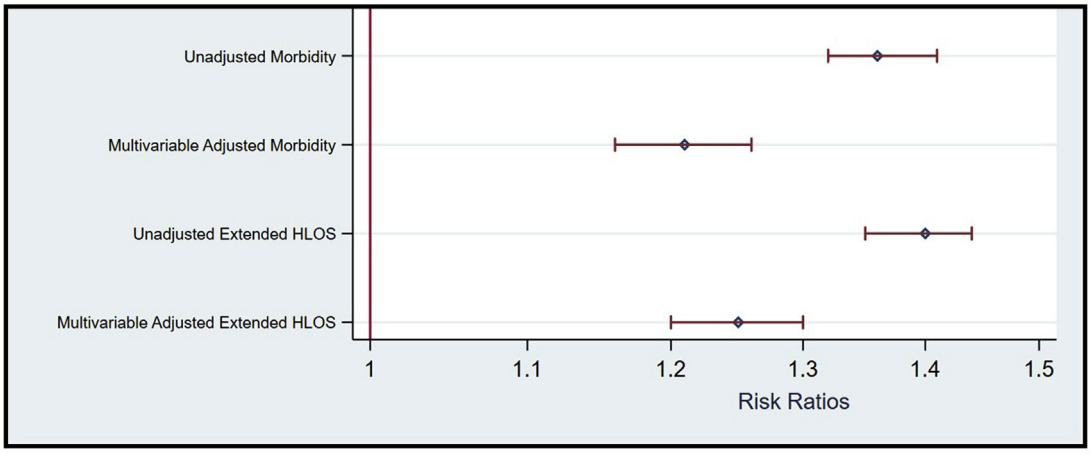
Table 3
Surgical outcomes and complication rates.

	Overall (N = 34,159)	AC (N = 17,315)	PR (N = 16,844)	*p*-value
Outcomes				
Overall morbidity (%)	27.3	23.1	31.5	<0.001
Overall mortality (%)	1.0	1.0	0.9	0.40
Extended hospital length of stay (%)	31.3	26.2	36.5	<0.001
Specific Complications	%	%	%	
Hematologic				
Transfusion	8.6	5.9	11.4	<0.001
Deep vein thrombosis	1.1	1.0	1.1	0.15
Pulmonary embolism	0.6	0.6	0.6	0.60
Surgical Site				
Superficial SSI	6.4	4.8	8.1	<0.001
Organ space SSI	6.6	7.0	6.1	<0.001
Deep SSI	1.9	0.9	2.8	<0.001
Cardiac				
Myocardial infarction	0.6	0.6	0.6	0.58
Cardiac arrest	0.4	0.4	0.4	0.47
Respiratory				
Pneumonia	1.8	1.7	2.0	0.03
Re-intubation	1.4	1.3	1.5	0.06
Prolonged vent >48 h	1.2	1.1	1.2	0.30
Infectious				
Postoperative sepsis	3.8	3.6	4.0	0.04
Urinary tract infection	3.9	3.3	4.6	<0.001
Septic shock	1.3	1.3	1.2	0.25
Neurologic				
Stroke	0.2	0.2	0.2	0.60
Renal				
Acute renal failure	0.6	0.6	0.5	0.30

AC=Abdominal-Colonic; SSI=surgical site infection
PR=Pelvic Rectal.

revealed significant discrepancy wherein high volume centers and specialist centers offered patients these same benefits of both improvements in short term morbidity and in long term oncologic outcomes. One of the ways that we expect the NAPRC to affect rectal cancer outcomes is through a focus on outcomes reporting through large national datasets. Currently there are multiple databases such as NSQIP and the National Cancer Database (NCDB), but each database measures separate outcomes and there is minimal overlap in the data that they collect. Although the NSQIP database does evaluate short term morbidity and mortality, it does not analyze rates of recurrence and disease free-survival. Accordingly, it is very relevant to access results from large nationwide databases in order to show that NAPRC accreditation confers the hypothesized advantages of improvements in short term morbidity and in long term oncologic outcomes.

The Procedure-Targeted Proctectomy NSQIP dataset was started in 2017 and includes important tumor-specific data points such as tumor location in the rectum, chemotherapy and radiation data, pre-treatment and pathologic TNM status, radial and distal margin status, and operative approach. Although this is an improvement compared to the standard NSQIP dataset, there are multiple patient and perioperative data missing. In addition, more specific data on



Unadjusted and Multivariable Adjusted Analysis of Surgical Outcomes in Pelvic-Rectal Cohort versus Abdominal-Colonic Cohort.
HLOS - Hospital Length of Stay

Fig. 1. Surgical outcomes for pelvic-rectal cohort.
Unadjusted and multivariable adjusted analysis of surgical outcomes in pelvic-rectal cohort versus abdominal-colonic cohort. HLOS-hospital length of stay.

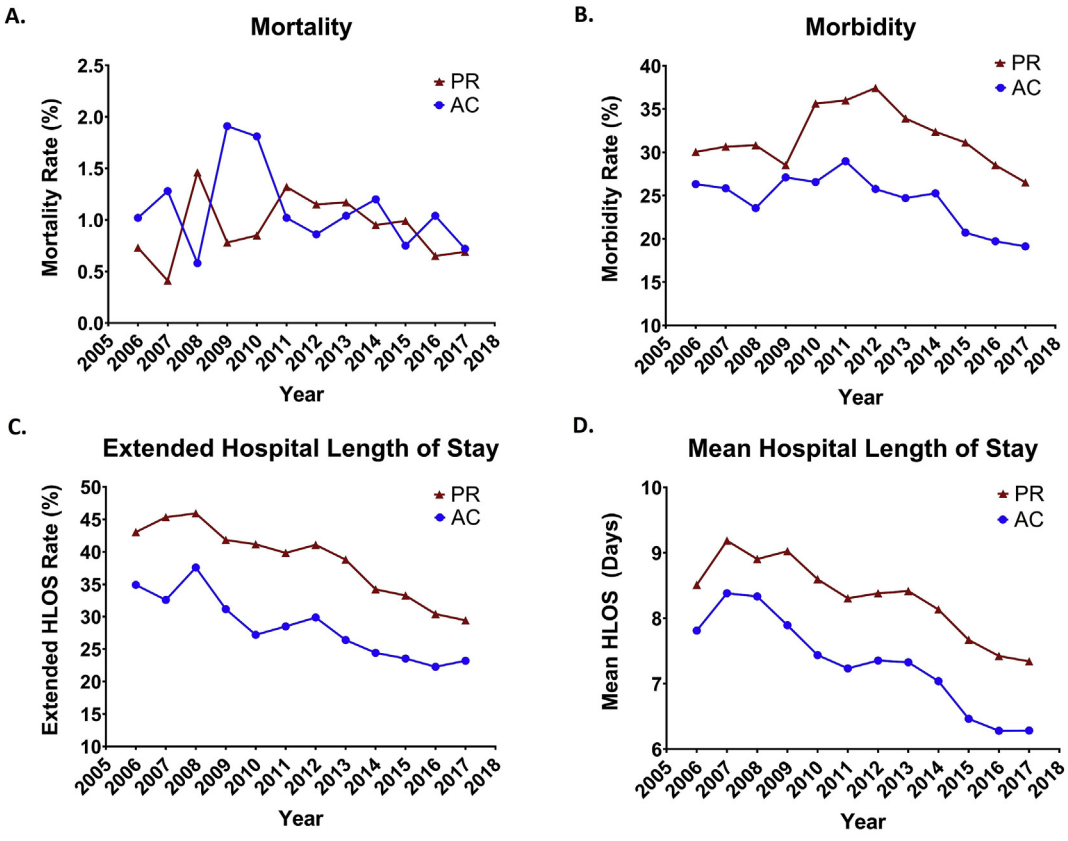


Fig. 2. Annual surgical outcomes.
PR-Pelvic/rectal cohort; AC-Abdominal/colonic cohort; HLOS-hospital length of stay.

chemotherapy and radiation regimens should be tracked. There is also very important tumor-specific data that is not being captured, such as lymphovascular invasion status, extramural vascular invasion status, threatened circumferential margin status, tumor regression grade, and presence or absence of complete clinical response. Ideally, the data between the standard NSQIP dataset, Procedure-Targeted Proctectomy NSQIP dataset, and the NCDB would be merged into a large central database in order to measure preoperative, perioperative, and postoperative outcomes not only from a surgical but also oncologic standpoint.

This study has several limitations related to the retrospective nature and study design. While NSQIP provides thousands of cases and hundreds of data points per case it has limited oncologic metric and lacks surgeon/hospital volume and patient geographic location. NSQIP tends to over-represent tertiary care centers and may not be applicable to all hospitals.[12] As a result, it is difficult to analyze the trends in care over the past decade on a national level. While the targeted proctectomy dataset offered in newer iterations of NSQIP provides oncologic metrics, there remains no information at the facility or surgeon level. Next, due to the retrospective nature of the study, we are only able to assess association, and not causation, between the preoperative risk factors and poor surgical outcome. Finally, a significant amount of critical information is not available through NSQIP such as specific disease characteristics, the individual clinical scenarios including the preoperative management of the patient and specific preoperative treatments such as chemotherapy regimens or radiation treatment. Despite these limitations, the strength of this study is in having accurate and validated clinical details coupled with outcomes data available for a large number of patients. These limitations re-emphasize a need for a more detailed centralized database for rectal cancer in order to further optimize rectal cancer management.

Conclusions

In conclusion, patients undergoing PR operations were more likely to have had major complications than were patients undergoing AC procedures; unfortunately no improvement in the rate of these complications or in mortality occurred. Significant reduction in HLOS was achieved without an increase in morbidity or mortality. Data were found to be lacking within NSQIP for several important variables including key oncologic data, stratification by surgical volume, and patient geographic location. We anticipate that the development of a large centralized rectal cancer database such as the NSQIP Procedure Targeted Proctectomy database as well as the NAPRC should help improve PR surgical and oncologic outcomes including decreasing rates of morbidity and mortality during the next decade.

Author contributions

SS, RM, MS, EA, AA, SS, BV, EL, SDW: substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; and drafting the work or revising it critically for important intellectual content; and final approval of the version to be published; and agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are

appropriately investigated and resolved.

Declaration of competing interest

All authors declare no relevant financial disclosures.

Acknowledgements

SPS: contributed to the study design, interpreted data, drafted and revised the manuscript.

RM: contributed to the study design, assisted in drafting and revising the manuscript.

MS: contributed to the study design, assisted in drafting and revising the manuscript.

EA: contributed to the study design, assisted in drafting and revising the manuscript.

AA: contributed to the study design, conducted analysis and interpretation of the data, assisted in drafting and revising the manuscript.

SCS: contributed to the study design, assisted in drafting and revising the manuscript.

BV: contributed to the study design, assisted in drafting and revising the manuscript.

EL: contributed to the study design, assisted in drafting and revising the manuscript.

SW: contributed to the study design, interpreted data, drafted and revised the manuscript.

All authors read and approved the final manuscript.

No financial conflict of interests to report.

Dr. Wexner and Dr. Sharp 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.

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