Predicting Opportunities to Increase Utilization of Laparoscopy for Rectal Cancer

Short title: Lap Rectal Cancer Predictors

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Abstract

Background: Despite proven safety and efficacy, rates of laparoscopy for rectal cancer in the US are low. With reports of inferiority with laparoscopy compared to open surgery, and movements to develop accredited centers, investigating utilization and predictors of laparoscopy are warranted. Our goal was to evaluate current utilization and identify factors impacting use of laparoscopic surgery for rectal cancer.

Methods: The Premier™ Hospital Database was reviewed for elective inpatient rectal cancer resections(1/1/2010-6/30/2015). Patients were identified by ICD-9-CM diagnosis codes, then stratified into open or laparoscopic approaches by ICD-9-CM procedure codes or billing charge. Logistic multivariable regression identified variables predictive of laparoscopy. The Cochran-Armitage test assessed trend analysis. The main outcome measures were trends in utilization and factors independently associated with use of laparoscopy.

Results: 3,336 patients were included- 43.8% laparoscopic(n=1,464) and 56.2% open(n=1,872). Use of laparoscopy increased from 37.6% to 55.3% during the study period($p<0.0001$). General surgeons performed the majority of all resections, but colorectal surgeons were more likely to approach rectal cancer laparoscopically(41.31% vs. 36.65%, OR 1.082, 95% CI[0.92, 1.27], $p<0.3363$). Higher volume surgeons were more likely to use laparoscopy than low volume surgeons(OR=3.72, 95%CI[2.64, 5.25], $p<0.0001$). Younger patients(OR 1.49, 95% CI[1.03, 2.17], $p=0.036$) with minor(OR 2.13, 95% CI[1.45, 3.12], $p<0.0001$) or moderate illness severity(OR 1.582, 95% CI[1.08, 2.31], $p<0.0174$) were more likely to receive a laparoscopic resection. Teaching hospitals(OR=0.842, 95% CI[0.710, 0.997], p=0.0463) and hospitals in the Midwest (OR=0.69, 95% CI[0.54, 0.89], p=0.0044) were less likely to use laparoscopy. Insurance status and hospital size did not impact use.

Conclusions: Laparoscopy for rectal cancer steadily increased over the years examined. Patient, provider, and regional variables exist, with hospital status, geographic location, and colorectal specialization impacting the likelihood. However, surgeon volume had the greatest influence. These results emphasize training and surgeon-specific outcomes to increase utilization and quality in appropriate cases.

Keywords: Laparoscopic colorectal surgery; rectal cancer; surgical quality; surgeon volume

Introduction

Laparoscopic colorectal surgery is the new standard of care and a key enabler of enhanced recovery programs (1). Despite the clinical benefits, reported rates of laparoscopic surgery for rectal cancer in the United States are low (2, 3). The reasons for the lower than expected utilization are multifactorial, including the long learning curve, technical challenges of working in an anatomically confined space, and limits in instrumentation and visibility (4–8). While the technique is difficult, no compromises in patient safety or oncological outcomes, including rate of conservative sphincter surgery, length of hospital stay, post-surgical complications, number of affected/isolated lymph nodes or affected circumferential and distal margins, were reported during the learning curve for laparoscopic rectal cancer resections (9). Another key reason for lower than expected utilization may be that the oncologic and long-term safety of the technique was unclear (10).

The safety and feasibility of laparoscopy was first proven for colon cancer (11–19); then, controlled studies were extended to rectal cancer. Several large case series and single-institution trials showed that laparoscopy was safe and feasible for rectal cancer (20). Results from the COLOR II, COREAN, and MRC CLASICC randomized-controlled trials supported equivalent outcomes for laparoscopic and open rectal cancer resections (16, 21–25). Findings from recent studies questioned these results. The long-term outcomes from the ALaCaRT and ASOCOG Z6051 trials demonstrated laparoscopic resection failed to meet the criterion for noninferiority compared with open surgery in curative rectal cancer resections (26, 27). With this lack of support for routine use of laparoscopic surgery, and movements to standardize techniques and develop centers of excellence, investigating current utilization and predictors of laparoscopy for rectal cancer resection are warranted.

Our goal was to evaluate the current utilization and identify factors impacting use of laparoscopic surgery for rectal cancer. Our hypothesis was that by identifying these factors, surgeons could proactively work to safely increase laparoscopic approaches and surgical quality for rectal cancer patients.

Methodology and Materials

The Premier Hospital Database (Premier, Charlotte, NC, USA) was reviewed from January 1, 2010 through June 30, 2015 to identify patients with rectal cancer who underwent elective rectal resection. The Premier Hospital Database represents approximately 1 out of every 5 United States inpatient hospital discharges, and is one of the largest hospital-level resource utilization and economic databases in the U.S. Specifically, there are approximately 600 hospitals contributing data on over 5 million inpatient discharges per year. Hospitals included in the database are a national representation in terms of regional distribution, urban versus rural hospital, teaching versus non-teaching institutions, and hospital bed size. Discharge-level data includes information on patient and provider characteristics, International Classification of Diseases 9th revision Clinical Modification (ICD-9-CM) diagnosis and procedure codes, hospital resource utilization such as specific device usage, medications and laboratory services, and charges/cost data on all entries.

Rectal cancer patients were identified by International Classification of Diseases, Ninth Revision [ICD-9] diagnosis codes (154.1 and 230.4). Patients were eligible and included if over 18 years of age and had an elective rectal resection performed via an abdominal approach. Patients were excluded if under 18 years of age, undergoing an emergent procedure, had metastatic disease, if rectal cancer was not the primary diagnosis, no resection was performed, or a procedure was performed via a robotic, anorectal, or endoscopic approach. Eligible patients were then stratified into laparoscopic or open groups based on ICD-9 procedure codes (laparoscopic 48.42, 48.51, 17.36 or open 46.04, 48.43, 48.52, 48.62, 48.64). For some ICD9 procedures codes (48.40, 48.50, 48.49, 48.59, 48.69, 48.63, 48.65) that were not able to differentiate open from laparoscopic alone, the presence of combination of laparoscopic ICD9 procedure code (54.21. 54.51) and billing data were used to further separate the laparoscopic procedure from open procedure. Laparoscopic converted to open patients were included in the laparoscopic cohort for intention to treat analysis.

Univariate analysis was used to compare the laparoscopic and open groups, with student t-tests and chi-squared statistics for continuous and categorical variables, respectively. A multivariable logistic regression model was used to identify variables predictive of use of laparoscopy for rectal cancer. The regression model was constructed adjusted for patient, provider and hospital characteristics. Variables evaluated in the analysis included patient age, gender, race, year of surgery (2010-2015), insurance status (Medicaid, Medicare, Private Commercial, Other), severity of illness (3M™ All Patient Refined DRG (APR

DRG) Classification System severity scores), hospital region (Northeast, Midwest, South, West), surgeon specialty, surgeon colon cases/year, urban vs. rural hospital, teaching vs. non-teaching private hospital, and hospital bed size. The APR-DRG severity of illness scale was used to provide an evaluation of resource use and clinical outcomes. (28). Adjusted Odds Ratios (OR) were reported for all the predictors included in the model, along with 95% confidence interval and p-value. The Cochran-Armitage test was used for trend analysis. P-value less than 0.05 was considered as statistically significance. All analyses were performed using SAS software, version 9.4 (Cary, NC).

The data in Premier are de-identified and compliant with the Health Insurance Portability and Accountability Act (HIPAA), and therefore exempt from Institutional Review Board (IRB) approval (45 CFR §46.001(b) (4)).

Results

3,336 patients were included in the analysis- 43.8% laparoscopic (n=1,464) and 56.2% open (n=1,872). Overall, the use of laparoscopy steadily increased from 37.6% to 55.3% during the study period, ($p<0.0001$). There were inherent differences in the patients undergoing each approach (Table 1). The laparoscopic cohort patients were significantly younger ($p<0.001$), with lower disease severity ($p<0.001$), and more privately insured patients than the open cohort ($p<0.001$). General surgeons performed the majority of all resections, but colorectal surgeons were more likely to approach rectal cancer laparoscopically (41.31% vs. 36.65%, p=0.023). High volume (> 20 cases per year) and medium volume physicians (10-20 cases per year) performed significantly more cases laparoscopic than open (p<0.001). There were regional differences seen in use of laparoscopy for rectal cancer. Most cases, both open (43.64%) and laparoscopic (43.99%) were performed in the South. There were significantly more open cases in the Midwest (19.66% open vs. 16.53% laparoscopic) and significantly more laparoscopic cases in the Northeast (22.34% laparoscopic vs. 18.70% open), (p=0.018). In the univariate analysis, there were no significant differences seen in case approach by hospital bed size, teaching status, or urban/ rural location. Full patient, surgeon, and hospital demographics from the univariate analysis are seen in Table 1.

Multivariable logistic regression was performed to identify variables predictive of use of laparoscopy for rectal cancer (Table 2). The odds of receiving laparoscopic surgery have steadily improved over the years. Younger patients (<50 years old) (OR 1.49, 95% CI [1.03, 2.17], p=0.036) and patients with minor (OR 2.13, 95% CI (1.45, 3.12), p<0.0001) or moderate illness severity (OR 1.582, 95% CI [1.08, 2.31], p<0.0174) were associated with higher odds of receiving a laparoscopic resection. While colorectal surgeons were more likely to approach a case laparoscopically than general surgeons, this association was not statistically significant after adjusting other covariates in the multivariable logistic analysis (OR 1.082, 95% CI[0.92, 1.27], p<0.3363). Higher volume surgeons were more likely to use laparoscopy than low volume surgeons (OR=3.72, 95%CI: [2.64, 5.25], p<0.0001). Teaching hospitals (OR=0.842, 95% CI [0.710, 0.997], p=0.0463) and hospitals in the Midwest region (OR=0.69, 95% CI [0.54, 0.89, p=0.0044) were less likely to use laparoscopy. Gender, insurance status, and hospital size did not independently impact use of laparoscopy for rectal cancer receiving laparoscopic surgery in the multivariable regression model ($p>0.05$).

Discussion

This is a turbulent time for laparoscopic surgery for rectal cancer. Early reports showed safety and efficacy of laparoscopy for curative rectal cancer resection, with equivalent oncologic endpoints (20, 29–35); controlled trials then affirmed similar 3-year overall survival, disease-free survival, and local recurrence compared to open surgery (16, 21–25). The adoption of minimally invasive approaches for rectal cancer resection continued to lag behind colon cancer (36). Then, recent reports of non-inferiority of laparoscopic resection compared with open resection for pathologic outcomes were published, concluding there sufficient evidence for the routine use of laparoscopic surgery (26, 27). Concurrently, there are national movements to improve outcomes and adherence to evidence-based guidelines through checklists, multidisciplinary tumor boards, and accredited centers of excellence (37–39). With these activities, defining the utilization and predictors of laparoscopy are warranted. Our goal was to evaluate the current utilization and identify factors impacting use of laparoscopic surgery for rectal cancer. We found use of laparoscopy increased during the study period, from 37.6% to 55.3%. From our results, there were identifiable patient, surgeon, and hospital factors that independently impacted likelihood of receiving a laparoscopic resection for rectal cancer. With these factors identified, surgeons can proactively work to safely increase laparoscopic approaches and surgical quality for rectal cancer patients.

Our study is a unique addition to the literature as no prior study has looked at the individual variables that are independently associated with use of a laparoscopic approach to curative rectal cancer resection. However, aspects of our results agree with previously published studies for improving outcomes in general for rectal cancer resection. A greater likelihood of laparoscopy in younger, less comorbid patients was found, which is an expected results; these factors have been widely seen in studies for colorectal cancer and described as a predictor of laparoscopy in colon cancer, but not previously for rectal cancer (40–42). In our study, surgeon specialty was an important predictive factor of laparoscopy, with colorectal surgeons 20% more likely to approach rectal cancer laparoscopically than general surgeons. While not focused on laparoscopy, prior studies have demonstrated the importance of surgeon specialization on outcomes, with colorectal surgeons and surgical oncologists having higher rates of restorative surgery [than colostomy formation] (43, 44) and improved overall survival (44–47). We also found geographic region was a significant predictor of use (and non-use) of laparoscopy, with the Midwest having the lowest rates. While not dedicated to laparoscopy, Monson et al. did find significant variation over 5-years study from the National Cancer Data Base in adherence to evidence-based rectal cancer guidelines across geographic regions (48). This variation in regional outcomes supports the development of rectal cancer centers of excellence in the US, where standardization could improve outcomes.

Our strongest predictor of laparoscopy for rectal cancer was surgeon volume. No previous study has looked at surgeon volume specifically related to laparoscopic use.

However, prior studies have shown the importance of volume on rectal cancer outcomes and surgical quality. Schrag et al reported that surgeon volume was the most important predictor of long-term survival, and remained an important predictor even after adjustment for hospital volume (49). Sphincter preservation has been reported as a surrogate for quality. Paquette et al found the most important predictor for sphincter preservation was high procedural volume (OR 1.55; 95% CI 1.33-1.79; $P < .001$) (50–52). Riccardi et al found 38.8% of surgeons in the US performed only nonrestorative procedures for rectal cancer; outcomes for these surgeons showed significantly higher mortality and longer length of stay compared those who performed both restorative and nonrestorative procedures (53). In reviewing a state-wide database over 5 years, Baek et al found only 8% (n = 24) of rectal cancer resections cases were performed at high-volume hospitals, however, there was significantly lower mortality and increased sphincter preservation in these higher-volume centers (50). The association between high-volume surgeons/ centers and improved outcomes supports referral to high-volume centers of excellence. (54).

Development of rectal cancer centers of excellence could integrate all of the factors that impact outcomes. Success has been proven in international models that regionalized care, standardized teaching and surgical techniques. The Norwegian Rectal Cancer Project increased the rate of total mesorectal excision, proportion of patients undergoing resection at high volume hospitals, increased rates of neoadjuvant therapy, reduced local recurrence, and increased survival for rectal cancer nationwide (55, 56). Similar improvements were seen with the Danish and Swedish National Rectal Cancer Registries, where care was centralized, local recurrence was reduced, and cancer related survival increased (57, 58, 58). The progression of regionalized centers of excellence and the National Accreditation Program for Rectal Cancer could be a potential avenue to improve overall outcomes and safety expand utilization of laparoscopy for rectal cancer in the US (59).

We recognize the limitations of this study. The largest limitation was the retrospective study design, which has inherent limitations. We also used a national inpatient administrative data source, which has the potential for selection biases and coding errors. In this large sample size, we would not expect these to make a significant impact on our results or conclusions. Further, the sample size provided by the national inpatient data source was necessary to have the power to find significant differences across approaches and determine the predictive models. In the model, we included surgeon volume as a candidate predictor, but not hospital volume, under the assumption that surgeon volume is correlated with hospital volume and does not need to be an additional variable. However, it is possible that hospital volume could also be a significant factor. Future work will examine the impact of this variable.

In conclusion, we found the use of laparoscopy for rectal cancer has steadily increased over the years examined. Patient, provider, and regional variables exist, with hospital status, geographic location, and colorectal specialization impacting the likelihood receiving laparoscopic rectal cancer surgery. However, surgeon volume had the greatest influence. These results emphasize the importance of training and surgeon specific outcomes to increase utilization, surgical quality, and improve patient recovery in appropriate cases.

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Table Legend

Table 1: Patient and Hospital Demographics for Laparoscopic and Open Rectal Cancer Resection

Table 2: Multivariable Logistic Regression Model for Variables Predictive of Laparoscopy in Rectal Cancer

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Appendix 1: Rectal Procedures and Stoma Codes
46.04 Resection of exteriorized segment of large intestine
48.40 Pull-through resection of rectum, not otherwise specified
48.42 Laparoscopic pull-through resection of rectum
48.43 Open pull-through resection of rectum
48.50 Abdominoperineal resection of the rectum, not otherwise specified
48.51 Laparoscopic abdominoperineal resection of the rectum
48.52 Open abdominoperineal resection of the rectum
48.49 Other pull-through resection of rectum
48.59 Other abdominoperineal resection of the rectum
48.69 Other resection of rectum, (Partial proctectomy, Rectal resection NOS)
48.62 Anterior resection of rectum with synchronous colostomy
48.63 Other anterior resection of rectum
48.64 Posterior resection of rectum
48.65 Duhamel abdominoperineal pull-through
17.36 Laparoscopic Sigmoidectomy

Patient and Hospital Demographics	MIS		OPEN		p-value
	n=1,464		*n=1,872*		
Patient characteristics	*N*	*Col. %*	*N*	*Col. %*	
Mean Age. Years (SD)	60.7 ± 11.9		62.8 ± 12.1		<0.0001
Age category					
Less than 50 years	298	20.36	295	15.76	<0.0001
51-60 years	448	30.60	553	29.54	
61-70 years	410	28.01	499	26.66	
71-80 years	221	15.10	379	20.25	

More than 80 years	87	5.94	146	7.80	
Gender					
Female	550	37.57	673	35.95	0.336
Male	914	62.43	1199	64.05	
Race					
Caucasian	1100	75.14	1275	68.11	
African American	89	6.08	146	7.80	0.0001
Hispanic	11	0.75	17	0.91	
Other	264	18.03	434	23.18	
Insurance Type					
Medicaid	90	6.15	157	8.39	<0.0001
Managed Care	707	48.29	750	40.06	
Other	117	7.99	151	8.07	
Medicare	550	37.57	814	43.48	
APR severity of illness					
Minor	619	42.28	596	31.84	<0.0001
Moderate	626	42.76	840	44.87	
Major	176	12.02	331	17.68	
Extreme	43	2.94	105	5.61	
Year of Surgery					
2015 (first 3 quarters)	120	8.20	97	5.18	<0.0001
2014	298	20.36	344	18.38	
2013	386	26.37	403	21.53	
2012	217	14.82	326	17.41	
2011	227	15.51	376	20.09	
2010	216	14.75	326	17.41	
Surgeon characteristics					
Physician specialty					
Colorectal surgeon	604	41.31	685	36.65	0.023
Other surgeon	101	6.91	142	7.60	
General surgeon	757	51.78	1042	55.75	
Physician Volume					
High (20 +/year)	138	9.44	56	3.00	<0.0001
Medium (10-20/year)	153	10.47	165	8.83	
Low (< 10 cases/year)	1171	80.10	1648	88.18	
Hospital characteristics					
Hospital Region					
Midwest	242	16.53	368	19.66	0.018
Northeast	327	22.34	350	18.70	
South	644	43.99	817	43.64	
West	251	17.14	337	18.00	
Teaching Hospital					
Non-Teaching Hospital	743	50.75	941	50.27	0.781
Teaching Hospital	721	49.25	931	49.73	

Bed Size					
500+ beds	651	44.47	781	41.72	0.242
250-500 beds	583	39.82	795	42.47	
<250 beds	230	15.71	296	15.81	
Urban vs rural					
Rural	113	7.72	159	8.49	0.417
Urban	1351	92.28	1713	91.51	

Table 1: Patient and Hospital Demographics for Laparoscopic and Open Rectal Cancer Resection

Variable (Reference Field)	Adjusted OR	95% CI of OR	p-value
Year of Surgery (2010)			
2015 (first 3 quarters)	1.856	(1.33, 2.58)	0.0002
2014	1.293	(1.02, 1.65)	0.0377
2013	1.435	(1.14, 1.81)	0.0022
2012	1.035	(0.80, 1.33)	0.7892
2011	0.918	(0.72, 1.17)	0.4947
Age category (>80y)			
Less than 50 years	1.493	(1.03, 2.17)	0.036
51-60 years	1.179	(0.83, 1.69)	0.3667
61-70 years	1.287	(0.94, 1.77)	0.1195
71-80 years	0.978	(0.71, 1.35)	0.8926
Gender (Male)- Female	1.02	(0.88, 1.18)	0.7922
Race (Caucasian)			
African American	0.772	(0.58, 1.03)	0.0766
Hispanic	0.979	(0.45, 2.15)	0.9574
Other	0.618	(0.51, 0.75)	<0.0001
Insurance Type (Medicare)			
Medicaid	0.745	(0.54, 1.04)	0.0791
Managed Care	1.09	(0.88, 1.36)	0.4366
Other	1.012	(0.74, 1.39)	0.9431
APR illness severity (Extreme)			
Minor	2.129	(1.45, 3.12)	0.0001
Moderate	1.582	(1.08, 2.31)	0.0174
Major	1.239	(0.83, 1.86)	0.3019
Surgeon specialty (General)			

Colon/rectal surgeon	1.082	(0.92, 1.27)	0.3363
Other surgeon	1.071	(0.81, 1.42)	0.634
Physician volume (Low)			
High (20 +/year)	3.724	(2.64, 5.25)	<0.0001
Medium (10-20/year)	1.2	(0.94, 1.54)	0.1524
Hospital Region (West)			
Midwest	0.694	(0.54, 0.89)	0.0044
Northeast	1.018	(0.79, 1.31)	0.8886
South	0.881	(0.71, 1.09)	0.2424
Teaching Hospital (Teaching)			
Non-Teaching Hospital	1.188	(1.00, 1.41)	0.0463
Bed Size (<250 beds)			
500+ beds	1.026	(0.81, 1.30)	0.8344
250-500 beds	0.907	(0.73, 1.13)	0.381
Urban vs rural (Urban)			
Rural	0.921	(0.69, 1.22)	0.5669

Table 2: Multivariate Logistic Regression Model for Variables Predictive of Laparoscopy in Rectal Cancer