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Intraoperative Anastomotic Evaluation Methods: Rigid Proctoscopy *Versus* Flexible Endoscopy

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ABSTRACT

Introduction: Rigid proctosigmoidoscopy (RP) and flexible sigmoidoscopy (FS) are two modalities commonly used for intraoperative evaluation of colorectal anastomoses. This study seeks to determine whether there is an association between the endoscopic modality used to evaluate colorectal anastomoses and the rate of anastomotic leak (AL), organ space infection, and overall infectious complication.

Methods: The 2012-2018 American College of Surgeons National Surgical Quality Improvement Program database was queried for patients undergoing colorectal anastomoses. Anastomotic evaluation method (RP *versus* FS) was identified by Current Procedural Terminologycoding and used for group classification. Outcomes measured included AL, organ space infections, and overall infection. Multivariable logistic regression analysis for predicting AL was performed.

Results: We identified 7100 patients who underwent a colorectal anastomosis with intraoperative endoscopic evaluation. RP was utilized in 3397 (47.8%) and FS in 3703 (52.2%) patients. RP was used more commonly in diverticulitis (44.5% *versus* 36.2%, $P < 0.01$), while FS was used more frequently in malignancy (47.5% *versus* 36.7%, $P < 0.01$). Anastomotic evaluation with FS was associated with lower rates of organ space infection (3.8% *versus* 4.8%, $P = 0.025$) and AL (2.9% *versus* 3.8%, $P = 0.028$) compared to RP. On multivariate logistic regression modeling, anastomotic evaluation with RP was associated with a higher risk of AL (odds ratio 1.403, 95% CI 1.028-1.916, $P = 0.033$) compared to FS.

Conclusions: Compared to FS, rigid proctosigmoidoscopic evaluation of a colorectal anastomosis was associated with an increased rate of AL and organ space infection.

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Introduction

Despite advances in surgical technique and postoperative care, anastomotic leak (AL) from a colorectal anastomosis remains a significant cause of morbidity and mortality.[1,2] Multiple modalities for evaluating a newly constructed anastomosis have been used with varying degrees of success, including mechanical air leak testing, direct anastomotic mucosal inspection, and fluorescence angiography.[3-8] In particular, the routine use of intraoperative endoscopy has been recommended in clinical practice, with Aly *et al.* finding an association between the use of intraoperative flexible endoscopy and a reduced rate of postoperative AL and anastomotic bleeding.[9-11]

Routine intraoperative evaluation of colorectal anastomoses via rigid proctosigmoidoscopy (RP) or flexible sigmoidoscopy (FS) has been used as methods for the evaluation of anastomotic integrity.[12] To our knowledge, no literature exists that compares the use of RP and FS with regards to AL outcomes in an intraoperative setting. The introduction of high-definition flexible endoscopy increases the likelihood that FS represents a superior method for anastomotic inspection.[13,14] Therefore, the aim of this study is to compare whether RP or FS is associated with increased anastomotic complications, such as AL.

Methods

In this retrospective review, we queried the American College of Surgeon's National Quality Improvement Procedure (NSQIP) -targeted colectomy database from 2012 to 2018 to identify patients who had undergone large bowel resection with construction of a colorectal anastomosis. Patients were identified using CPT codes 44145 (colectomy, partial, with coloproctostomy) and 44207 (laparoscopy, surgical; colectomy, partial, with anastomosis, with coloproctostomy) in addition to CPT codes listed below for FS and RP. Patients with CPT codes 44146 (colectomy, partial, with coloproctostomy, with colostomy) and 44208 (laparoscopy, surgical; colectomy, partial, with coloproctostomy, with colostomy) were excluded from the study. Patients were then stratified into groups based on endoscopic evaluation method: 1) RP and 2) FS. The following CPT codes were used to identify patients that underwent RP: 45300, 45303, 45305, 45307, 45308, 45309, 45315, 45317, 45320, 45321, and 45327. The following CPT codes were used to identify patients that underwent FS: 45330-45335, 45337, 45338, 45340, 45341, 45342, 45346, 45347, 45349, 45350, 45378-45382, 45384, 45385, 45386, 45388-45393, and 45398. This study was approved by the American College of Surgeons and the institutional review board at the University of California, Irvine Medical Center. Written consent was not required for approval as patient information was deidentified.

As indicated in the NSQIP database, AL was defined as a leak of endoluminal contents, such as air, fluid, or gastrointestinal contents, through an artificial anastomosis. This definition also encompassed any infection/abscess that was thought to be related to the anastomosis or any instance of contrast extravasation from the anastomosis, as indicated by the surgeon. Organ space infection (OSI) was defined as an infection that involved any part of the anatomy, other than the surgical site infection (SSI), that was open or manipulated during the operative procedure. An infection was defined as any occurrence of sepsis, superficial incisional SSI, deep incisional SSI, and OSI. The primary outcomes measured in the study were AL and OSI, and secondary outcomes that were measured included overall infection.

Demographic variables collected were age, sex, race, Hispanic ethnicity, operation year, comorbidities, functional health status, and chemotherapy exposure within 90 d prior to surgery. Comorbidities included diabetes, chronic obstructive pulmonary disease , congestive heart failure , hypertension, smoker status, chronic steroid use, 10% loss of body weight within 6 mo, and renal failure. Preoperative serum creatinine levels and preoperative serum albumin were also reported. Clinical variables collected were primary indication for surgery, operative approach, elective *versus* emergent surgery status, total operation time, American Society of Anesthesiologist (ASA) classification, mechanical bowel preparation, oral antibiotic preparation, and pathological TNM staging of any cancer patient when applicable. Variables for primary indication for surgery were grouped into succinct variable, including diverticulitis (both acute and chronic diverticulitis), malignancy (colon cancer and colon cancer with obstruction), inflammatory bowel disease (Crohn's disease and ulcerative colitis), nonmalignant polyp, and other (bleeding, enterocolitis, volvulus, other International Classification of Diseases-10 codes, and unknown diagnoses). Postoperative outcome variables collected were AL, superficial incisional SSI, deep incisional SSI, OSI, urinary tract infection, myocardial infarction, need for blood product transfusion, sepsis, unplanned reoperation, unplanned readmission, and length of hospital stay.

Descriptive statistics were performed for all variables. Continuous variables were plotted graphically to determine distribution normality. Mann–Whitney *U*-test was used to compare continuous variables, and chi-square test was used to compare categorical variables for bivariate analysis. Categorical data were reported as percentages, and continuous data were reported as medians with interquartile range. A multivariate logistic regression model was used to compare the primary outcome AL after the magnitude of association for predictor variables (age, sex, race, comorbidities, functional health status, prior chemotherapy, steroid use, surgery indications, and operative approach), and AL was measured. The same approach was performed for the previously defined OSI and infection. Two-tailed *P*-values were calculated and reported for all primary comparisons. Statistical significance was noted when $P < 0.05$. All data acquisition and statistical analysis for the project was carried out using the Statistical Analysis System software, version 9.4 (Statistical Analysis SystemInstitute, Inc, Cary, NC).

Results

A total of 7100 of patients underwent colectomy with endoscopic evaluation, of which 3397 patients (47.85%) who were evaluated by RP and 3703 patients (52.15%) who were evaluated by FS. Demographic characteristics of each group are detailed in Table 1. Demographic characteristics were similar between both groups, except for race, functional health status, renal failure, ASA classification, steroid use, weight loss over time, and chemotherapy exposure. Of note, the FS group had a significantly higher percentage of patients with higher ASA classification (FS class 3: 44.9% *versus* RP class 3: 40.8%, FS class 4: 2.5% *versus* RP class 4: 2.2%, $P < 0.01$). As shown in Figure, RP was more commonly used in the earlier years of the

Table 1 – Demographics characteristics and basal patient characteristics.

	Rigid proctosigmoidoscopy	Flexible sigmoidoscopy	P
	N = 3397	N = 3703	
Mean age, median (IQR)	60 (51, 69)	60 (51, 69)	0.11
Hispanic, *n* (%)	217 (6.4)	293 (7.9)	0.09
Sex, *n* (%)			0.95
Female	1742 (51.3)	1896 (51.2)	
Male	1655 (48.7)	1807 (48.8)	
Race, *n* (%)			0.01
White	2647 (77.9)	2886 (77.9)	
Black	206 (6.1)	290 (7.8)	
Asian	137 (4)	128 (3.5)	
Other	25 (0.7)	31 (0.8)	
Missing	382 (11.3)	368 (9.9)	
Functional health status, *n* (%)			<0.01
Independent	3284 (96.7)	3631 (98.06)	
Partially dependent	30 (0.9)	48 (1.3)	
Totally dependent	2 (0.06)	2 (0.05)	
Missing	81 (2.4)	22 (0.6)	
Comorbidities, *n* (%)			
Diabetes	408 (12.0)	493 (13.3)	0.11
COPD	115 (3.4)	119 (3.2)	0.70
CHF	13 (0.4)	12 (0.3)	0.70
Hypertension	1564 (46.0)	1665 (45.0)	0.40
Renal failure	6 (0.2)	1 (0.03)	0.045
Smoker	560 (16.5)	653 (17.6)	0.20
ASA classification, *n* (%)			<0.01
1	84 (2.5)	75 (2.0)	
2	1850 (54.5)	1870 (50.5)	
3	1387 (40.8)	1664 (44.9)	
4	75 (2.2)	91 (2.5)	
Unknown	1 (0.03)	3 (0.08)	
Primary indication, *n* (%)			<0.01
Diverticulitis	1513 (44.5)	1339 (36.2)	
Inflammatory bowel disease	26 (0.77)	34 (0.92)	
Malignancy	1246 (36.7)	1758 (47.5)	
Nonmalignant polyp	99 (2.9)	140 (3.8)	
Other	513 (15.1)	432 (11.7)	
Steroid use, *n* (%)	137 (4.0)	112 (3.0)	0.02
Weight loss, *n* (%)	144 (4.2)	113 (3.1)	<0.01
Dialysis, *n* (%)	11 (0.3)	16 (0.4)	0.46
Chemotherapy, *n* (%)	246 (7.2)	441 (11.9)	<0.01
Median serum creatinine* (IQR)	0.84 (0.7, 1.0)	0.82 (0.7, 1.0)	0.32
Median serum albumin* (IQR)	4.0 (3.7, 4.3)	4.0 (3.7, 4.3)	0.55

IQR = interquartile range; COPD = chronic obstructive pulmonary disease; CHF = congestive heart failure.
*Preoperative values in mg/dL units.

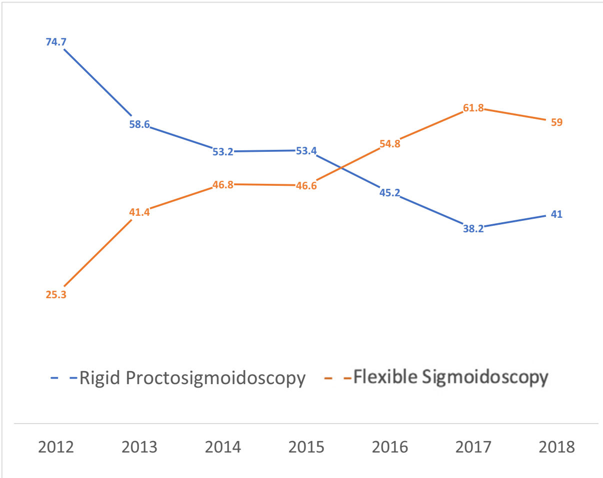

Fig. – Trend of endoscopic evaluation methods over study period years.

2012-2018 study, such as in 2012 (RP: 74.7% *versus* FS: 25.3%, $P < 0.01$) and in 2013 (RP: 58.6% *versus* FS: 41.4%, $P < 0.01$). FS, however, was more commonly used in the later years of the study, such as in 2017 (FS: 61.8% *versus* RP: 38.2%, $P < 0.01$) and in 2018 (FS: 59.0% *versus* RP: 41.0%, $P < 0.01$).

Operative characteristics of each group are detailed in Table 2. Compared to FS, RP had a higher percentage of diverticulitis diagnosis (44.5% *versus* 36.2%, $P < 0.01$). However, compared to RP, FS had a higher percentage of malignancy diagnosis (47.5% *versus* 36.7%, $P < 0.01$). Patients in the FS group more commonly underwent a robotic approach for surgery (21.6% *versus* 12.7%, $P < 0.01$) compared to the RP group. Patients in the FS group had a higher percentage of more severe ASA classification (ASA 3: 44.9% *versus* 40.8%; ASA 4: 2.5% *versus* 2.2%, $P < 0.01$) compared to the RP group. The median total operation time in the FS group was higher compared to the RP group (221 min *versus* 188 min, $P < 0.01$). Patients in the FS group had a higher rate of mechanical bowel preparation (80.2% *versus* 75.9%, $P < 0.01$) compared to patients in the RP group. Patients in the RP group had a higher percentage of oral antibiotic preparation (55.1% *versus* 50.0%, $P < 0.01$) compared to the FS group. The pathological TNM staging characteristics are also provided in Table 2 when a diagnosis of malignancy is documented.

Postoperative characteristics of each group are detailed in Table 3. Primary outcomes, including AL and OSI, were analyzed. The total AL rate for the entire patient cohort was 3.3% (237/7100). AL was significantly higher in the RP group compared to the FS group (3.8% *versus* 2.9%, $P = 0.028$). The total OSI rate was 4.3% (303/7100). Patients in the RP group also

Table 2 – Perioperative characteristics.

	Rigid proctosigmoidoscopy	Flexible sigmoidoscopy	P
	N = 3397	N = 3703	
Operative approach, *n* (%)			<0.01
Laparoscopic	2085 (61.4)	2144 (57.9)	
Robotic	431 (12.7)	801 (21.6)	
Open	549 (16.2)	474 (12.8)	
Conversion*	280 (8.2)	250 (6.8)	
Other	52 (1.5)	34 (0.92)	
Mechanical bowel prep, *n* (%)	2261 (75.9)	2385 (80.2)	<0.01
Oral antibiotic prep, *n* (%)	1640 (55.1)	1515 (50.0)	<0.01
Elective surgery, *n* (%)	3077 (90.6)	3366 (90.9)	0.74
Median operation time (IQR), min	188 (138, 252)	221 (169, 290)	<0.01
Pathological T stage, *n* (%)†			0.49
T0	56 (4.5)	105 (5.6)	
T1	171 (13.7)	233 (13.4)	
T2	267 (21.4)	361 (20.7)	
T3	564 (45.1)	775 (44.4)	
T4	129 (10.3)	168 (9.6)	
Pathological N stage, *n* (%)†			0.70
N0	708 (56.2)	964 (55.1)	
N1	350 (27.8)	481 (27.5)	
N2	143 (11.3)	223 (12.8)	
Pathological M stage, *n* (%)†			0.12
M0	582 (64.2)	895 (67.2)	
M1	55 (6.1)	91 (6.8)	

IQR = interquartile range.
*Ltablefaparoscopic or robotic surgery converted to open surgery.
†Patients diagnosed with malignancy only.

Table 3 – Postoperative clinical outcomes.

	RP	FS	P
	N = 3397	N = 3703	
Anastomotic leak, *n* (%)	130 (3.8)	107 (2.9)	0.028
Superficial SSI, *n* (%)	112 (3.3)	127 (3.4)	0.83
Deep incisional SSI, *n* (%)	18 (0.53)	21 (0.57)	0.54
Organ space SSI, *n* (%)	164 (4.8)	139 (3.8)	0.025
Urinary tract infection, *n* (%)	70 (2.1)	71 (1.9)	0.67
Myocardial infarction, *n* (%)	10 (0.29)	13 (0.35)	0.67
Bleeding transfusions, *n* (%)	176 (5.2)	183 (4.9)	0.64
Sepsis, *n* (%)	150 (4.4)	112 (3.0)	<0.01
Infection*, *n* (%)	329 (9.7)	325 (8.8)	0.18
Unplanned reoperation, *n* (%)	162 (4.8)	137 (3.7)	0.33
Unplanned readmission, *n* (%)	263 (7.7)	318 (8.6)	0.051
Length of hospital stay, d (IQR)	4 (3, 6)	4 (3, 6)	0.97

SSI = surgical site infection; IQR = interquartile range.
* Defined as occurrences of sepsis, superficial incisional surgical site infection (SSI), deep incisional SSI, and organ space SSI.

had a higher percentage of OSI (4.8% *versus* 3.8%, $P = 0.025$) and a higher percentage of sepsis occurrences (4.4% *versus* 3.0%, $P < 0.01$) compared to patients in the FS group.

An adjusted multivariate logistic regression analysis for predicting risk of postoperative outcomes based on method of endoscopic evaluation method is reported in Table 4. On multivariate regression, RP patients experienced 1.4 times the risk of developing an AL compared to FS (OR: 1.403, 95% confidence interval 1.028-1.916, $P = 0.033$). The associated risk of developing OSI or infection was not statistically significant.

Discussion

Both RP and FS can be used for intraoperative evaluation of left-sided colorectal anastomoses.[12] However, with the technological advancements of high-definition flexible endoscopy, FS has become more widely used over time, as reflected in our data, with an increasing percentage of FS being utilized every year. Our review demonstrated that RP assessment of a colorectal anastomosis was associated with an increased rate of postoperative AL compared to FS evaluation. The results using data from a national surgical outcomes database also provides insight into the evolving surgical trends practiced by the surgical community.

Routine intraoperative endoscopic evaluation has been recommended for surgeons performing a left-sided colorectal anastomosis.[9-12] Our results demonstrate that the use of RP is associated with increased rates of AL, OSI, and sepsis compared to FS endoscopic evaluation. To our knowledge, this study represents the first national surgical outcome database review that shows FS is associated with a decreased risk for anastomotic complications compared to RP. The total AL rate in this study (3.3%) was within the reported AL rates for colorectal anastomoses (3% to 19%) as described in recent randomized controlled trials and systematic reviews, although on the lower range.[1,6,15-17] This lower AL rate is likely due to ALs being captured in the OSI variable, which occurred at a total rate of 4.3%. The definition of OSIs includes intra-abdominal and pelvic abscesses, which may be the result of an AL. We also found that FS was associated with a decreased rate of postoperative OSI and sepsis compared to RP, confirming the significance of these findings related to endoscopic evaluation. Patients in the FS group still maintained a decreased rate of AL and OSIs, despite having operative characteristics suggesting increased risk of anastomotic complications. For example, compared to the RP group, patients evaluated by FS were more commonly found to have a higher ASA classification, which represents a surrogate for increased operative difficulty and increased risk for anastomotic complications.[18]

It is possible that FS is associated with a decreased rate for AL because of the favorable technological features offered by flexible endoscopy compared to RP. All the current literature studies comparing RP and FS examine the efficacy of endoscopic evaluation methods with respect to malignancy localization or anorectal disease treatment, performed in the outpatient setting.[19-21] In a prospective study proposing a simple endoscopic grading system, Sujatha Bhaskar *et al.* described an intraoperative evaluation method using a flexible endoscope for stratifying a colorectal anastomosis into three different tiers for predicting AL risk.[4] To date, Sujatha Bhaskar *et al.*'s study is the only endoscopic grading method available that mandates the use of a flexible endoscope, which cannot be achieved with RP, as flexible endoscopy offers precise, high-definition visual examination of a newly fashioned anastomosis.[4] A surgeon has improved ability with high-definition FS to visualize the perianastomotic mucosa for risk factors such as congestion or ischemia that may lead to revision of a high-risk and/or tenuous anastomosis.[4,10,22] However, it is possible that FS is being used simply to distend the anastomosis for a mechanical leak test and identify any obvious defects or leaks at the anastomosis.[5] RP, which is an inflexible, hollow device, is relatively immobile, which may lead to the operating surgeon missing questionable-appearing anastomoses that need revision.[14,19,20] Much like FS, RP can be reliably used as a conduit for air insufflation to perform a mechanical leak test.

Table 4 – Adjusted logistic regression analysis for risk of various outcomes for patients undergoing RP *versus* FS.

	Odds Ratio	95% confidence interval	P value
Anastomotic leak	1.403	1.028-1.916	0.033
Organ space SSI	1.019	0.689-1.505	0.927
Infection*	0.979	0.744-1.288	0.877

SSI = surgical site infection.
* Defined as occurrences of sepsis, superficial SSI, deep incisional SSI, and organ space SSI.

Our study also provides insight into the evolving surgical trends that are being practiced in the surgical community for patients undergoing a colorectal anastomosis. During our study period from 2012 to 2018, we found that patients in the earlier years (2012-2015) underwent RP more often than FS, while in the later years (2016-2018) surgical practice transitioned to favoring FS. This trend towards the increased use of FS may reflect the surgical community's increased acceptance and familiarity with flexible endoscopy, given the technological advancements of high-definition FS and the more diverse residency/fellowship training of surgeons.[13,23] However, this trend in use of endoscopic evaluation methods in favor of FS may also be coincidental with the natural evolution in surgical practice associated with AL prevention, as progress in the AL understanding has led to the development of advanced protocols for preventing AL.[12,24] In addition, RP was more commonly used to evaluate a colorectal anastomosis when the operation was done for the treatment of diverticulitis, while FS was more commonly employed when the indications were for malignancy. This statistic likely reflects the inherent differences in the surgical specialty/training of each operating surgeon. Colorectal malignancies are more often resected by a fellowship-trained colorectal surgeon after their initial outpatient workup, as opposed to a general surgeon.[25-27] Throughout the literature, surgeons subspecialized in colorectal surgery have been shown to have better clinical outcomes, including improved overall survival in the treatment of colon and rectal cancer.[28-30] Colorectal surgeons' expertize in the treatment of colorectal malignancy likely translated into the improved surgical outcomes seen in our study.[28-30] It is unknown, however, whether the decreased rate of AL or OSI is due to fellowship-trained colorectal surgeons performing the operation rather than the FS technique that was employed for anastomotic inspection. Unfortunately, the NSQIP dataset did not include surgical subspecialty training to delineate fully whether FS was employed more by a colorectal surgeon *versus* a general surgeon.

This study should be considered with certain limitations. Our study involved a retrospective national database, which relies on accurate documentation and classification. Demographics and clinical characteristics collected were limited to what was available in the NSQIP database, which did not include surgical subspecialty training. We do not have information on technical factors of the operation, including the use of intracorporeal *versus* extracorporeal anastomosis, number of stapler fires, intraoperative anastomosis revision, tumor height, or anastomosis level. We also do not have the exact indications for intraoperative endoscopic use, which may have been for reasons other than visual anastomotic inspection, such as assessment of tumor height, distance from the anal verge, or mechanical air leak testing of the anastomosis.

Conclusions

The use of RP, compared to FS for anastomotic evaluation, was associated with an increased rate for postoperative anastomotic complications. Large randomized prospective studies are needed to determine the superiority of RP *versus* FS for anastomotic evaluation.

Disclosure

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Statements and Declarations

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