ORIGINAL CONTRIBUTION

A Laparoscopic Approach Does Reduce Short-Term Complications in Patients Undergoing Ileal Pouch-Anal Anastomosis

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BACKGROUND: Studies to date examining the impact of laparoscopy in the IPAA have failed to demonstrate a significant, consistent benefit in terms of a reduction in short-term morbidity or length of stay.

OBJECTIVE: The aim of this study was to establish the impact of the operative approach (laparoscopic or open) on outcomes after IPAA formation.

DESIGN, SETTING, AND PATIENTS: With use of the American College of Surgeons National Surgical Quality Improvement Program participant use file (2005–2008), the records of patients who underwent open or laparoscopic IPAA with diverting ileostomy were examined.

MAIN OUTCOME MEASURES: Risk-adjusted 30-day outcomes and length of stay were assessed by use of regression modeling, adjusting for patient characteristics, comorbidities, and operative approach.

RESULTS: Six hundred seventy-six cases were included, of which 339 (50.1%) were laparoscopic procedures. After adjustment, a laparoscopic approach was associated with a lower rate of major (OR = 0.67, 95% CI: 0.45–0.99, P = .04) and minor (OR = 0.44, 95% CI: 0.27–0.70, P = .01) complications. Laparoscopy was not associated with a significant reduction in length of postoperative stay compared with open pouch formation (laparoscopic vs open approach, -0.05 ± 0.30 d (P = .87)).

LIMITATIONS: The sampling strategy used by the National Surgical Quality Improvement Program means that only a proportion of all relevant cases would have been analyzed and no data are available about the potential impact of surgeon experience on outcome.

CONCLUSIONS: A laparoscopic approach to ileal pouch formation was associated with a significant reduction in both major and minor complications compared with the traditional open approach. Given the high financial costs associated with complications arising from this procedure, this study provides support for the adoption of the laparoscopic approach in the formation of an IPAA.

KEY WORDS: Ileal pouch-anal anastomosis; Laparoscopy.

Restorative proctocolectomy with IPAA has become the operation of choice for the majority of patients with ulcerative colitis (UC) and familial adenomatous polyposis (FAP).[1] Long-term follow-up studies have confirmed good functional outcome and high patient satisfaction in most patients.[2,3] However, IPAA performed with the traditional open approach is associated with a short-term operative morbidity of up to 30%.[2,3] The adoption of a laparoscopic approach for colonic resection in both malignancy and diverticular disease has been shown to significantly reduce both short-term complications and length of stay compared with the standard open approach.[4,5] Intuitively, one would anticipate that a similar reduction in morbidity would be afforded by the laparoscopic approach in the construction of an IPAA given the significant morbidity associated with the traditional open approach. However, the studies to date have failed to demonstrate a significant, consistent benefit in terms of short-term morbidity or length of stay.[6,7]

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Maartense et al[6] reported no significant difference in terms of short-term complications between a laparoscopic assisted (20% morbidity rate) and open approach (17%) in the only randomized trial reported to date. Operative time was significantly longer in the laparoscopic assisted (mean, 210 min) compared with the open group (mean, 133 min) with no significant reduction in postoperative length of stay. A recent systematic review of 11 studies (n = 607) confirmed that a laparoscopic approach was associated with a significantly longer operative time with no significant difference in complications compared with open IPAA.[7]

It should be noted that the largest single case matched series reported to date contained only 100 laparoscopic cases and only 41% (n = 253) of the patients included in the systematic review underwent a laparoscopic approach. Given the fact that the laparoscopic approach has been reported to be associated with higher overall costs compared with the open approach, it is important to establish whether laparoscopic IPAA can offer a meaningful advantage compared with the standard open approach.[6] The aims of this study were to assess the impact of operative approach on the 30-day complication rate and length of stay in patients undergoing IPAA with use of the American College of Surgeons National Surgical Quality Improvement Program (NSQIP) database.

METHODS

The American College of Surgeons NSQIP comprises a clinical database with systematic data collection conducted at hundreds of hospitals throughout the United States. Details of the NSQIP sampling strategy, data abstraction, parameters collected, and outcomes recorded have been previously reported.[8] In brief, the program collects information pertaining to patient demographics, preoperative medical history, clinical findings, and laboratory investigations. Postdischarge follow-up data are obtained both from chart review and a standardized phone interview with the patient by a certified nurse reviewer with the intention of capturing complications up to 30 days postoperatively. The sampling strategy used for case capture in NSQIP requires reporting of the first 40 consecutive general surgery cases (including colorectal procedures) on an 8-day cycle such that the subsequent cycle starts on a different day of the week to ensure capture of a variety of cases.[9] High-volume intermediate procedures (eg, inguinal herniorraphy, lumpectomy) are limited to 3 cases per cycle to maximize the number of major procedures eligible for inclusion. Hospitals are required to capture at least 20% of their surgical case volume in each surgical subspecialty.[9]

The NSQIP database was queried for patients with a primary postoperative diagnosis of UC or FAP based on the International Classification of Disease, 9th Edition.[10] The primary diagnosis category was then cross-referenced with the Current Procedural Terminology (CPT) codes to identify only patients with UC or FAP who had undergone an IPAA.[10] Case selection was limited to CPT codes that coded for total colectomy with proctectomy, creation of ileoanal anastomosis with loop ileostomy, and rectal mucosectomy, when performed in adult patients (≥16 y). The relevant codes were 44157, 44158 (open IPAA), and 44211 (laparoscopic IPAA). CPT code 45113 was not included because this code captures cases with and without a diverting loop ileostomy and it is not possible to be definitive about the presence of a diverting ostomy in the analysis of such cases.

Patient characteristics such as sex, age, operative indication (FAP vs UC), presence of obesity (defined as body mass index (BMI) ≥30), smoking status, and history of weight loss were included in the analysis. Preoperative comorbidity variables were grouped by organ system (cardiac, pulmonary, history of diabetes, hepatic, and neurologic) and preoperative steroid use within 1 month of surgery was also analyzed. Preoperative functional status was not included in the analysis because of the small number of patients with a dependent functional status (n = 7). Preoperative anemia (defined as a hematocrit <36) and the preoperative albumin level were examined. Operative factors such as wound classification, ASA score, intraoperative blood transfusion, and duration of operative procedure were included in the analysis. Postoperative clinical complications were grouped by organ system and then categorized as either major or minor. Major complications included organ space (peritoneal) infections, cardiac events, ventilator dependence (reintubation or failure to wean), pneumonia, venous thromboembolic events, return to the operating room, renal failure, and sepsis. Minor complications included surgical site infections (superficial to the fascia) and urinary tract infections.

In addition to the categorical occurrence or absence of a postoperative complication, the occurrence of such an event before initial patient discharge was calculated by comparing the days from the operation until the event and the postoperative length of stay. Postoperative length of stay was defined as the days from the operation until discharge and was examined as a continuous outcome variable.

Differences in the clinical characteristics of the patient groups based on operative procedure were assessed using a *t* test with pooled or unpooled variances, a Wilcoxon rank-sum test, or χ^2, as appropriate to the data. Major and minor complications were independently evaluated as binary outcomes and the associations of operative approach and surgical risk factors with these outcomes were examined in univariate (unadjusted) and multivariate (adjusted) logistic regressions. Those variables with a *P* value of ≤.10 in the univariate model were selected for inclusion in the multivariate logistic regressions. A total of 6 variables were incorporated in the multivariate model for major complications. These were operative approach (laparoscopic vs open), operative indication (FAP vs UC), intraoperative

TABLE 1. Clinical characteristics of the patient population

	Total population	*Laparoscopic group*	*Open group*	*P*
Total group	676	339 (50.1%)	337 (49.9%)	
Diagnosis (UC)	592 (87.6%)	293 (86.4%)	299 (88.7%)	.36
Male sex	393 (58.1%)	182 (53.7%)	211 (62.6%)	.02
Mean age in years	40.1 (±4.6)	39.0 (±14.4)	41.2 (±13.9)	.04
BMI ≥30	151 (22.3%)	61 (18.0%)	90 (26.7%)	.01
Current smoker within 1 y	72 (10.7%)	38 (11.2%)	34 (10.1%)	.64
>10% weight loss in prior 6 mo	41 (6.1%)	23 (6.8%)	18 (5.3%)	.43
History of diabetes mellitus	26 (3.9%)	10 (3.0%)	16 (4.8%)	.24
Cardiac comorbidity	109 (16.1%)	51 (15.0%)	58 (17.2%)	.44
Pulmonary comorbidity	6 (0.9%)	3 (0.9%)	3 (0.9%)	.99
Hepatic insufficiency	3 (0.4%)	0 (0.0%)	3 (0.9%)	.08
Renal insufficiency	0 (0.0%)	0 (0.0%)	0 (0.0%)	—
Neurologic comorbidity	5 (0.7%)	2 (0.6%)	3 (0.9%)	.65
Steroids for chronic condition	279 (41.3%)	148 (43.7%)	131 (38.9%)	.21
Bleeding disorders	8 (1.2%)	6 (1.8%)	2 (0.6%)	.016
Mean preoperative albumin	2.4 (±1.9)	2.2 (±2.0)	2.7 (±1.9)	.01
Mean preoperative serum WBC	7.8 (±3.8)	7.9 (±4.0)	7.7 (±3.5)	.51
Mean preoperative platelet count	310.3 (±167.5)	341.7 (±135.4)	341.5 (±120.7)	.99
Preoperative HCT (<36)	241 (35.7%)	120 (35.4%)	121 (35.9%)	.89
ASA class III, IV, + V	127 (18.8%)	53 (15.6%)	74 (22.0%)	.04
Intraoperative transfusion	40 (5.9%)	13 (3.9%)	27 (8.0%)	.02
Wound class III or IV	87 (12.9%)	34 (10.0%)	53 (15.7%)	.03
Total operation time (≥335 min) (75th centile)	170 (25.2%)	124 (36.6%)	46 (13.7%)	<.0001
Mean days from operating room to discharge	7.6 (±4.6)	7.3 (±4.3)	7.9 (±4.8)	.09

Categorical variables represented as frequency as well as incidence in respective population, continuous variables as means ± SD.
UC = ulcerative colitis; BMI = body mass index; WBC = white blood cell count; HCT = hematocrit.

blood transfusion, preoperative cardiac comorbidity, preoperative steroids, and BMI ≥30. Only 2 variables (operative approach and patient sex) were incorporated in the multivariate model for minor complications.

Univariate and multivariate linear regression models incorporating perioperative variables as well as the occurrence of a predischarge major or minor complication were used to evaluate the effect of these clinical factors on the postoperative length of stay. All analyses were conducted at the University of Rochester using SAS 9.2 (SAS Institute Inc., Cary, NC) on a Windows XP Pro platform.

RESULTS

A total of 676 IPAA cases with diverting ileostomy were included overall, of which 339 (50.1%) were laparoscopic procedures. The clinical characteristics and operative findings are outlined in Table 1. There were a total of 211 major complications recorded in the 30-day study period which involved 141 patients (20.9% of total group) and 98 minor complications in 90 patients (13.3%). On univariate analysis a laparoscopic approach was associated with a reduction in the number of patients who developed any major complication (OR = 0.66, 95% CI: 0.45–0.95, $P = .03$) in the 30-day postoperative period compared to an open IPAA (Table 2). Laparoscopic IPAA was also associated with a lower 30-day minor complication rate compared to the open procedure (OR = 0.50, 95% CI: 0.31–0.80, $P = .01$).

The relationship between preoperative comorbidities, intraoperative factors, and postoperative major complications was then examined. A total of 6 different variables were incorporated into the multivariate model and are listed in the methods. The factors significantly associated with major and minor complications are outlined in Table 3. Of note, ASA class was not associated with a higher rate of major ($P = .51$) or minor complications ($P = .87$) on univariate analysis and was not included in the multivariate analysis. BMI ≥30 was not associated with an increase in major complications on multivariate analysis (OR = 1.27, 95% CI: 0.80–2.01, $P = .3$). After adjustment, a laparoscopic approach was still associated with a lower rate of major (OR = 0.67, 95% CI: 0.45–0.99, $P = .04$) and minor (laparoscopic vs open: OR = 0.44, 95% CI: 0.27–0.70, $P = .01$) complications. A subgroup analysis confined to patients with ASA ≤2 and BMI <30 was also performed (n = 437). There was no significant association between operative approach and major complications (laparoscopic vs open) (OR = 0.6, 95% CI: 0.35–1.00, $P = .05$). A laparoscopic approach, however, was associated with a significant reduction in minor complications compared with an open procedure (OR = 0.47, 95% CI: 0.26–0.85, $P = .01$).

On unadjusted analysis, the mean postoperative length of stay was not significantly shorter for the laparoscopic group (7.3 ± 4.3 d) compared to the open group (7.9 ± 4.8 d) ($P = .09$). Multivariate regression analysis demonstrated that laparoscopy was not associated with a

TABLE 2. Thirty-day rates of major and minor complications by operative approach

Complications	*Subgroups*	*Laparoscopic IPAA (n = 339)*	*Open IPAA (n = 337)*	*OR (95% CI)*	*P*
Total number of major complications		84 (24.8%)	127 (37.7%)		
Major complications					
	Deaths	1 (0.3%)	2 (0.6%)	0.50 (0.02–5.20)	.57
	Respiratory	4 (1.2%)	6 (1.8%)	0.66 (0.17–2.33)	.52
	Cardiac	1 (0.3%)	0 (0.0%)		
	VTE	9 (2.7%)	11 (3.3%)	0.81 (0.32–1.98)	.64
	Renal failure	0 (0.0%)	10 (3.0%)		
	Organ space infection	24 (7.1%)	36 (10.7%)	0.64 (0.37–1.09)	.10
	Sepsis	19 (5.6%)	37 (11.0%)	0.48 (0.27–0.85)	.01
	Return to operating room	24 (7.1%)	22 (6.5%)	1.09 (0.60–2.00)	.78
No. of patients with ≥1 major complication(s)		59 (17.4%)	82 (24.3%)	0.66 (0.45–0.95)	**.03**
Total number of minor complications		36 (10.6%)	62 (18.4%)		
Minor Complications					
	UTI	17 (5.0%)	17 (5.0%)	1.0–	.99
	Incisional infection	19 (5.6%)	45 (13.4%)	0.39 (0.22–0.66)	.01
No. of patients with ≥1 minor complication(s)		32 (9.4%)	58 (17.2%)	0.50 (0.31–0.80)	**.01**

The relationship between operative approach and complications was analyzed for the number of patients with one or more complication(s) only, rather than the total number of complications, because many of the end points are interrelated. An odds ratio could not be provided for cardiac complications or renal failure because there were no events in one of the groups in each case.
VTE = venous thromboembolism; UTI = urinary tract infection.

significant reduction in length of postoperative stay compared with open IPAA (laparoscopic vs open approach, -0.05 ± 0.30 d ($P = .87$)). Factors independently associated with a prolonged postoperative stay are outlined in Table 4.

DISCUSSION

This study has demonstrated that laparoscopic IPAA is associated with a significant reduction in both major and minor complications compared with the conventional open approach. It is important to note that there were some significant baseline differences between the laparoscopic and open groups. Compared with patients who underwent laparoscopic IPAA, more patients who underwent open IPAA were male, were older, had a higher ASA class, and were more likely to have a contaminated wound (wound class III or IV). Because baseline clinical differences exist between patients in the laparoscopic and open group, it is essential to control for potential confounding factors when examining the relationship between operative approach and the overall rate of 30-day complications.

The total operating time was significantly longer in the laparoscopic group (median total operating time, 298 min) compared with the open group (median operating time, 229 min), in accordance with previous reports.[7,11] It is interesting to note that the rate of intraoperative transfusion was significantly lower in the laparoscopic group. This may correlate with previous reports that have shown a lower rate of intraoperative blood loss when the laparoscopic approach is utilized.[11,12]

The relationship between operative approach and complications was analyzed on the basis of the number of patients with a major complication rather than the total number of complications, because many of the end points

TABLE 3. Adjusted (multivariate) analysis of factors associated with major and minor complications

	OR (95% CI) [*P* value]	
	Major complications	*Minor complications*
Laparoscopic vs open approach	0.67 (0.45–0.99) [.04]	0.44 (0.27–0.70) [.01]
Male vs female	—	0.45 (0.28–0.71) [.01]
Operative indication (FAP vs UC)	0.43 (0.18–0.90) [.04]	—
Intraoperative blood transfusion	2.43 (1.22–4.76) [.01]	—
Cardiac comorbidity	1.74 (1.05–2.83) [.03]	—

FAP = familial adenomatous polyposis; UC = ulcerative colitis.

TABLE 4. Multiple regression analysis for days from operation until discharge following IPAA

Factor	*Days from operation until discharge ± SE*	*P*
Laparoscopic vs open approach	−0.05 ± 0.30	.87
Preoperative hepatic insufficiency: yes vs no	+12.22 ± 2.24	<.0001
BMI (≥ 30 vs <30)	+0.96 ± 0.36	<.01
Intraoperative blood transfusion: yes vs no	+1.66 ± 0.63	.01
Predischarge minor complication vs none	+3.45 ± 0.74	<.0001
Predischarge major complication vs none	+7.40 ± 0.54	<.0001

BMI = body mass index.

(sepsis, organ space infection, and return to the operating room) are undoubtedly interlinked. It was believed that analyzing cases on the presence or absence of any major complication(s) would provide a more meaningful assessment of the impact of operative approach on outcome. Although laparoscopic IPAA was associated with a marked reduction in the number of patients with a major complication, postoperative sepsis was the only end point where it was associated with a significant reduction compared with open IPAA. Pelvic sepsis is a relatively common acute complication after IPAA formation; it occurs in 5% to 10% of cases and is associated with a 5-fold risk of long-term pouch failure.[13] Septic complications can be caused by an anastomotic dehiscence or an infected pelvic hematoma.[14] It is conceivable that, because the laparoscopic approach was associated with a significantly lower rate of intraoperative blood transfusion in this analysis and with less intraoperative blood loss in other studies, that a laparoscopic approach may be associated with a lower propensity for the formation of pelvic hematoma.[12] Intraoperative blood loss is not recorded in the NSQIP database and it is difficult to draw definitive conclusions on the putative reasons why a laparoscopic approach was associated with a significant reduction in postoperative sepsis. Intraoperative blood transfusion was associated with an increased risk of major complications, in keeping with the report of Kiran et al[15] and Madbouly et al[16] who found that both intraoperative and postoperative blood transfusions were independently associated with septic complications post IPAA. It has been suggested that allogenic blood transfusions may induce deleterious immunomodulatory effects leading to an increased risk of bacterial infection.[17] However, an intraoperative transfusion may be simply a surrogate marker for a case complicated by a significant hemorrhage requiring a transfusion that would increase the risk of a postoperative pelvic hematoma and hence sepsis. A diverting ostomy is often used electively to reduce the risk of pelvic contamination in the event of a subsequent anastomotic dehiscence.[18] In this study, only cases coded as incorporating a diverting ostomy were included because the absence of a diverting ostomy has been reported to be associated with a higher risk of anastomotic leakage and subsequent pelvic sepsis in some series.[19]

The finding that a preoperative diagnosis of FAP was associated with a lower rate of major complications compared with UC is in accordance with previous reports.[15,20] A history of cardiac comorbidity was found to be independently associated with a higher rate of major postoperative complications. This is in keeping with a previous analysis of colorectal surgery cases from the NSQIP database that found preoperative comorbidity contributed to the preoperative statistical risk modeling of morbidity after colorectal surgery.[21,22]

A laparoscopic approach was associated with a marked reduction in postoperative minor complications, which was attributable to a risk reduction of 56% in incisional wound infections compared with the conventional open IPAA. A similar reduction in incisional infections was also seen in the subgroup analysis of patients who were not obese (BMI <30) and low ASA class (I and II). This is in keeping with similar reductions in the rate of incisional wound infection rates seen following the adoption of a laparoscopic approach for colorectal cancer and diverticular disease.[4,5] This is in contrast with the systematic review that found no benefit in terms of a reduction in wound infections afforded by a laparoscopic approach to IPAA.[7,11] This may reflect the capture of a large number of incisional wound infections in the 30-day data follow-up of the NSQIP protocol where 69% of all minor complications in this study occurred in the postdischarge setting. The relatively high incidence of urinary tract infections (UTIs) in female patients (10%) underlines the importance of prompt catheter removal because a prolonged period with an indwelling catheter (more than 2 days postoperatively) has been shown to be associated with an increased risk of a UTI.[23]

There was no significant difference in the adjusted length of stay between the laparoscopic and open groups on the initial admission. The length of overall postoperative length of stay (mean, 7.6 d) reflects the complex nature of the surgery with the attendant complications and need for ostomy education before discharge. A more widespread adoption of "fast-track" postoperative care pathways and preoperative ostomy education for patients may help reduce the postoperative length of stay post-IPAA.[24,25] Both major and minor complications were significantly associated with a prolonged length of stay post-IPAA in accordance with previous studies.[26,27] Although a laparoscopic approach did not reduce the initial hospital stay, the significant reduction in postdischarge complications should offer a significant financial advantage. Swenson et al have previously reported that an episode of pelvic sepsis added $9268 to an episode of care and an incisional wound infection after open colorectal surgery has been estimated to cost approximately $6200 in community nursing costs.[26,28]

It is important to acknowledge certain limitations of the NSQIP dataset. We have no information on the level of experience or subspecialty interest of the surgeons involved. It is conceivable that the surgeons who were undertaking cases laparoscopically were more likely to be specialist, high-case-volume colorectal surgeons. This may account for the difference in outcomes seen between the 2 groups, but it is impossible to be definitive about the impact of surgeon expertise on the observed results because this information is not available. There were baseline differences between the 2 groups; patients in the open group were significantly more likely to be obese and male, and have a higher ASA class, which may well reflect a selection bias. It is possible that surgeons opted for a laparoscopic approach in thinner, healthier (lower ASA class) patients

and reserved the open approach for more challenging cases (male patients with obesity and higher ASA class). Obesity has been previously reported to be associated with an increase in infectious complications post-IPAA, although a BMI >30 was not independently associated with either major or minor complications in the current study.[15,29,30] The apparent selection bias in our cohort must be acknowledged as a putative factor in the differences in outcome seen between the 2 groups. It is not possible from the coding to ascertain whether the cases were done to completion laparoscopically or with the assistance of a hand port, although it is unclear whether there is any significant benefit afforded by one laparoscopic approach over the other.[31]

Although NSQIP offers data on a large number of pre- and postoperative variables, no data are available for certain variables of interest such as anastomotic leak and the reason for return to the operating room. The sampling strategy used by NSQIP means that the cases analyzed represent only a proportion of the total number of IPAA procedures performed in the participating institutions and reflects only the case mix of the hospitals who use the NSQIP system to audit their activity. Thus, the findings may not be reflective of the general population of hospitals across the United States. However, this study offers an insight into the short-term outcome of the largest number of laparoscopic IPAA cases reported to date. The strength of the NSQIP dataset is that it offers the opportunity to examine the 30-day outcome in a cohort of patients where both preoperative and postoperative factors are collected in a consistent and validated manner.

This study found that in the NSQIP dataset patients selected for a laparoscopic approach to IPAA had a significantly lower rate of 30-day major and minor complications compared with open restorative proctocolectomy. A laparoscopic approach may help reduce the morbidity associated with ileal pouch formation in appropriately selected patients. The observed reduction in complications with their attendant costs provides support for the adoption of the laparoscopic approach in IPAA formation.

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