

# Evaluation of One-Stage Laparoscopic-Assisted Restorative Proctocolectomy at a Specialty Center: Comparison with the Open Approach

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**PURPOSE:** This study compared outcomes after laparoscopically assisted and open restorative proctocolectomy performed as a one-stage procedure, including anorectal mucosectomy and omission of ileal diversion.

**METHODS:** We reviewed our prospectively maintained database of patients who underwent restorative proctocolectomy between 1998 and 2006. Demographic data, surgical indications, and intraoperative and postoperative complications were evaluated. Anastomotic leaks were identified by radiologic, endoscopic, or intraoperative evidence. The primary outcome variables were complications, duration of operation, blood loss, intraoperative spillage of enteric contents, and the ability to complete the procedure in one stage.

**RESULTS:** One-stage laparoscopically assisted restorative proctocolectomy was performed in 50 patients and open restorative proctocolectomy was performed in 155 patients. The mean operative time was longer for the laparoscopically assisted group (198.7 vs. 159.1 minutes;  $P = 0.006$ ). The mean estimated blood loss was less among the patients in the laparoscopically assisted group (287.5 vs. 386.4 ml;  $P = 0.006$ ). There were no significant differences in intraoperative or postoperative complications between the two groups.

**CONCLUSIONS:** Laparoscopically assisted one stage restorative proctocolectomy is a safe and technically

feasible procedure. There seems to be no increase in the rate of postoperative complications compared with the open approach. Laparoscopically assisted restorative proctocolectomy should be considered in the surgical management of patients who require this procedure.

**KEY WORDS:** Laparoscopy; Restorative proctocolectomy; J-pouch; Ulcerative colitis.

Laparoscopically assisted colorectal resection may have significant benefits compared with the open approach. Recent reports have suggested that among appropriately selected patients, minimally invasive techniques are associated with less postoperative pain, improved cosmesis, and lower long-term complication rates.<sup>1-9</sup> Despite these data, there are only limited studies evaluating the role of laparoscopy in restorative proctocolectomy (RPC). A few small series have suggested that laparoscopically assisted RPC may be a safe alternative to conventional RPC.<sup>1-9</sup> However, these series have been limited by relatively small numbers. Additionally, the majority of the patients included in these reports underwent a two-stage procedure, including the routine use of diverting ileostomy and stapled anastomoses.

To date, there is no large comparative study evaluating open and laparoscopic one-stage restorative proctocolectomy, including routine anorectal mucosectomy and omission of diverting ileostomy. The purpose of this study was to compare short-term outcomes among patients who underwent one-stage laparoscopically assisted and open RPC.

## PATIENTS AND METHODS

Patients undergoing restorative proctocolectomy by a single practice at The Mount Sinai Medical Center were prospectively entered into a computerized database that

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has been maintained since 1987. This database captures patient demographics (*i.e.*, age, sex, indication for RPC, duration of disease, and preoperative immunosuppressive regimen) and operative details, including complications.

Since 1992, it has been our practice to attempt one-stage RPC, including anorectal mucosectomy and hand-sewn ileoanal anastomosis, for all suitable candidates. Selection criteria for one-stage RPC have been previously reported.<sup>10</sup> One-stage RPC is considered in the elective setting when the patient is nutritionally intact, and immunosuppression is limited to prednisone 20 mg (or equivalent) or less. Use of 6-mercaptopurine, methotrexate, cyclosporine A, or infliximab is not considered a contraindication to one-stage RPC. Patients who require urgent or emergent surgery are not considered candidates for one-stage RPC. The final decision regarding omission of temporary ileostomy is made by the operating surgeon at the time of surgery and is based on factors that include the integrity of the ileal pouch-anal anastomosis. One-stage laparoscopically assisted RPC has been offered to highly selected patients since 1998. Selection criteria are the same as those used in open surgery.

Open RPC was performed through a vertical midline incision extending from the pubis to a point between 3 and 10 cm above the umbilicus. The first ten laparoscopically assisted RPC cases were performed by using the hand-assisted approach with placement of three laparoscopic ports. All subsequent laparoscopically assisted RPCs were performed through four laparoscopic ports without the hand-assist device. These ports included a 10 mm port inserted at the umbilicus and 5 mm ports inserted in the epigastric region, and the right and left lower quadrants. Mobilization of the right, transverse, descending, and sigmoid colon was completed laparoscopically by using the harmonic scalpel and bipolar tissue sealing and cutting device. Once the colon was adequately mobilized, it was exteriorized through a low Pfannenstiel incision. Division of the colon mesentery, rectal dissection, and construction of the ileal J-pouch were completed through this incision. Mucosectomy was performed transanally using minimal anal retraction and precise dissection. The completed pouch was delivered through this incision to the perineal surgeon for creation of the handsewn, ileal J-pouch-anal anastomosis. If mesenteric length was deemed inadequate to effectuate a handsewn anastomosis, then mucosectomy was omitted and the double-stapled technique was used. Two closed suction drains were placed in the pelvis near the anastomosis. The pouch was decompressed with a transanal catheter. All patients received standard perioperative intravenous antibiotics. Stress dose steroids were administered based on preoperative steroid intake and subsequently tapered postoperatively.

The patients evaluated in this study were identified from the database. The intention in all cases was to

perform one-stage RPC. Demographic data, surgical indications, and intraoperative and postoperative complications were extracted from the database. The main outcomes of interest were complication rates, length of operating time, blood loss, intraoperative spillage of enteric contents, anastomotic tension, and the ability to complete the procedure in one stage. We postulated that given the limited pelvic access afforded by a Pfannenstiel incision, laparoscopically assisted RPC would be associated with more complications, specifically, more anastomotic leaks. This might be a result of greater rates of spillage of enteric contents, higher rates of anastomotic tension, or both in laparoscopically assisted cases.

Anastomotic tension was subjectively assessed by the perineal surgeon at the time of surgery. This was an overall assessment of the ease with which the pouch could be brought to the dentate line. The presence or absence of anastomotic tension was recorded at the time of surgery. Spillage of enteric contents during mucosectomy and pouch delivery to the dentate line also was recorded. Additional data were gathered by chart review and patient interviews. Anastomotic leaks were identified by radiologic, endoscopic, or intraoperative evidence.

We compared the laparoscopic and open groups by using chi-squared, Fisher's exact test, and Mann-Whitney *U* tests. Student's *t*-test was used to compare means. Calculations were made using the SPSS 15.0 for Windows software package.  $P < 0.05$  was considered statistically significant. The study was approved by the Mount Sinai School of Medicine Institutional Review Board.

## RESULTS

A total of 395 patients underwent RPC between January 1998 and May 2006. Of these, 142 had had a preceding subtotal colectomy. Two hundred fifty-three patients had surgery with the intent to perform a one-stage RPC. Of these, 196 patients had an open RPC and 57 patients had a laparoscopically assisted RPC.

RPC was completed in one stage in 205 cases (50 laparoscopically assisted, 155 open). Immediate diversion was performed in 48 (19 percent) instances. The proportions of primarily diverted patients were similar between the laparoscopically assisted and open groups (7/57 vs. 41/196;  $P = 0.18$ ). Anastomotic tension was significantly more common in the diverted group (20/48 vs. 19/205;  $P < 0.0001$ ). However, the mean body mass index (BMI) was similar (22.4 vs. 23.4 kg/m<sup>2</sup>;  $P = 0.526$ ). Diverted patients were older (42.5 vs. 37.7 years;  $P = 0.027$ ) and were more commonly men (35/48 vs. 110/205;  $P = 0.016$ ). Diagnoses were similar between diverted and undiverted cases. However, among colitic patients ( $n = 238$ ) duration of disease was longer among the diverted patients (15.3 vs. 10.1 years;  $P = 0.006$ ). Usage of

**TABLE 1.** Comparison of demographic variables between the laparoscopic and open groups

Demographic variable	Laparoscopic RPC	Open RPC	P value
Total no. of patients	50	155	
Female gender	37 (74)	58 (37.4)	<0.001
Mean age (yr)	32.0 (12–57)	39.5.5 (15–70)	<0.001
Mean BMI (kg/m <sup>2</sup> )	21.8 (15.5–33.9)	22.6 (17.6–37.6)	0.603
Mean duration of colitis (yr)	8.7 (1–24)	10.7 (0.8–44)	0.215
Preoperative immunomodulator use	35 (76.1)	99 (67.8)	0.358
Prednisone	18 (41.5)	75 (50.2)	0.177
6-mercaptopurine	24 (27.1)	60 (36.5)	0.233
Cyclosporine	5 (11.3)	18 (10.8)	1

RPC = restorative proctocolectomy; BMI = body mass index.

Data are numbers with percentages or ranges in parentheses unless otherwise indicated.

preoperative immunomodulators was similar for diverted and undiverted patients.

Among the one-stage cases, the laparoscopically assisted group contained more women (37/50 vs. 58/155;  $P < 0.001$ ) and was younger (mean age 32 vs. 39.5 years;  $P < 0.001$ ). The mean BMI was similar for both groups (21.8 vs. 22.6 kg/m<sup>2</sup>;  $P = 0.215$ ). Among those patients with colitis ( $n = 192$ ), the preoperative duration of disease was similar between the laparoscopically assisted and open groups (8.7 vs. 10.7 years;  $P = 0.08$ ). Preoperative use of immunomodulators among patients with colitis was similar between the two groups (35/46 vs. 99/146;  $P = 0.358$ ). The demographics of the two groups are listed in Table 1, and the indications for RPC are summarized in Table 2. There was no statistically significant difference between the two groups with regard to surgical indication. Dysplasia was found preoperatively in 9 patients (18 percent) in the laparoscopic group and 43 patients (27.7 percent) in the open group ( $P = 0.194$ ). In addition, adenocarcinoma was found in one patient (2 percent) in the laparoscopic group and nine (5.8 percent) in the open group ( $P = 0.0456$ ).

The mean operative time was longer for the laparoscopically assisted group (198.7 vs. 159.1 minutes;  $P = 0.006$ ). The estimated blood loss was less (287.5 vs. 386.4 ml;  $P = 0.006$ ) among the patients in the laparoscopically assisted group. Spillage of enteric contents and tension on the anastomosis were similar between the two groups (Table 3). The median incision length among the laparoscopically assisted patients was 11.4 (range,

6.1–24.1) cm. In all laparoscopically assisted cases, the colon was mobilized using laparoscopic techniques. There were no conversions.

Among one-stage patients, leakage at the ileal pouch-anal anastomosis occurred in four (8 percent) of the laparoscopically assisted cases and 11 (7.1 percent) of the open cases. This difference was not significant (4/50 vs. 11/155;  $P = 0.763$ ). The average length of hospital stay was not significantly different between the laparoscopically assisted (mean, 10.5 (range, 7–20) days) and the open groups (mean 10.1 (range, 3–33) days;  $P = 0.601$ ). The rate of postoperative complications was not statistically different between the two groups (Table 4). Secondary diverting ileostomy was performed in 3 of 50 (6 percent) patients in the laparoscopically assisted group and 14 of 155 (9 percent) patients in the open group. This difference was not statistically significant ( $P = 0.76$ ). Indications for secondary diversion included anastomotic leak during the early postoperative period in all 3 patients in the laparoscopically assisted group and 12 patients in the open group. An additional two patients in the open RPC group were secondarily diverted: one for intractable diarrhea and another after multiple failed repairs of a pouch-anal anastomotic defect. Both of these patients ultimately required pouch excision.

## DISCUSSION

Compared with open surgery, laparoscopically assisted RPC takes longer to perform but involves smaller blood

**TABLE 2.** Indications for restorative proctocolectomy

Indication for RPC	Laparoscopic RPC (n = 50) n (%)	Open RPC (n = 155) n (%)	P value
Ulcerative colitis	46 (92)	139 (90)	NS
Familial adenomatous polyposis	4 (8)	9 (5.8)	NS
Crohn's disease	0 (0)	4 (2.6)	NS
Indeterminate colitis	0 (0)	3 (1.9)	NS

NS = not significant.

**TABLE 3.** Comparison of intraoperative variables between the laparoscopic and open groups

Intraoperative variable	Laparoscopic RPC (n = 50)	Open RPC (n = 155)	P value
Mean operative time (min)	198.7 (158–564)	159.2 (104–363)	0.006
Estimated blood loss (ml)	287.5 (100–600)	386.4 (150–1700)	0.006
Spillage of enteric contents	9 (18)	34 (21.9)	0.69
Tension on anastomosis	5 (10)	14 (9)	0.785
Stapled anastomosis	2 (4)	20 (12.9)	0.113

RPC = restorative proctocolectomy.

Data are numbers with percentages or ranges in parentheses unless otherwise indicated.

loss. Complication rates, hospital stay, and ability to complete RPC without diversion are similar between laparoscopic and open groups. These results suggest that laparoscopically assisted restorative proctocolectomy as a one-stage procedure is a safe and feasible alternative to the open procedure. However, these findings must be tempered by the fact that this study examined non-randomized and highly selected subsets of patients.

Our findings are similar to those reported elsewhere. Outcomes of open and laparoscopic or hand-assisted RPC have been compared in several retrospective or case-controlled studies<sup>1–9</sup> (Table 5). As in the present study, these studies reported no differences in complication rates and pouch loss. One randomized, controlled trial compared outcomes between open and hand-assisted approaches. This study also found no differences between the groups, except for longer operative time with the hand-assisted cases.<sup>5</sup> These findings are similar to those of a recent meta-analysis, which evaluated studies that compared short-term outcomes between laparoscopic and open RPC.<sup>11</sup>

Unlike previous studies, we examined the results of laparoscopically assisted RPC where a one-stage procedure was the intent in all instances. Since 1992, we have omitted routine diverting ileostomy from RPC procedures and reported an 8 percent rate of anastomotic leakage, a rate not significantly higher than those who underwent primary fecal diversion.<sup>9</sup> Subsequent reports have confirmed that a diverting ileostomy after handsewn or stapled ileal pouch-anal anastomosis does not reduce the incidence of anastomotic leak.<sup>10,12–14</sup> It is our current

practice to reserve diversion for patients with identifiable risk factors for anastomotic failure, such as malnutrition, preoperative weight loss, high-dose steroid usage, technical difficulties with the anastomosis, and significant intraoperative contamination.

The Pfannenstiel incision used in laparoscopically assisted cases was considered a potential impediment to a tension-free pouch-anal anastomosis. Limited access also might have contributed to a higher rate of spillage of intestinal contents during pouch delivery. Therefore, it was postulated that these factors might increase the frequency of primary diversion. However, the rate of primary diversion at RPC was not increased in the laparoscopically assisted group. One-stage RPC was accomplished in nearly 81 percent of cases, with similar numbers reaching this goal among laparoscopically assisted and open cases. Rates of anastomotic tension and spillage also were similar for the two groups.

In the largest case-matched series published to date, 100 laparoscopically or hand-assisted RPC procedures were compared with 200 open RPC cases.<sup>8</sup> Larson and colleagues<sup>8</sup> found that minimally invasive techniques were associated with longer operative time and a significantly shorter hospital stay relative to open RPC. Complications rates were similar for open and laparoscopic groups. We also found that minimally invasive techniques required more time to perform and resulted in similar complication rates. However, our data demonstrated that postoperative length of hospitalization was the same regardless of operative approach to RPC. This discrepancy is probably secondary to our standardized

**TABLE 4.** Comparison of postoperative complications in laparoscopic and open groups

Postoperative complication	Laparoscopic RPC (n = 50)	Open RPC (n = 155)	P value
Small-bowel obstruction	10 (17.8)	34 (21.9)	0.845
Wound infection	3 (6)	11 (7.1)	1
Bleeding	1 (2)	3 (1.9)	1
Fever	10 (20)	24 (15.5)	0.512
Anastomotic leak	4 (8)	11 (7.1)	0.763
Urinary tract infection	1 (2)	0 (0)	0.244

RPC = restorative proctocolectomy.

Data are numbers with percentages in parentheses unless otherwise indicated.

**TABLE 5.** Summary of studies comparing open, laparoscopic-assisted, and hand-assisted restorative proctocolectomy

Study, year	Study design	OR time	Primary fecal diversion	LOS (days)	Complications
Schmitt <i>et al.</i> , 1994 <sup>1</sup>	Case-matched lap (22) vs. open (20)	Longer for Lap	NR	8.7 vs. 8.9 (NS)	NS
Marcello <i>et al.</i> , 2000 <sup>2</sup>	Case-matched lap (20) vs. open (20)	Longer for Lap	Lap (60%) Open (65%)	7 vs. 8 ( $P < 0.05$ )	NS
Brown <i>et al.</i> , 2001 <sup>3</sup>	Retrospective lap (13) vs. open (12)	Longer for Lap	All patients	7.5 vs. 8 (NS)	NS
Hashimoto <i>et al.</i> , 2001 <sup>4</sup>	Retrospective HAL (11) vs. lap (13)	Longer for Lap	All patients	24.1 vs. 31.3 ( $P < 0.05$ )	NS
Rivadeneira <i>et al.</i> , 2004 <sup>5</sup>	Retrospective HAL (10) vs. lap (13)	Longer for Lap	Majority of HAL and Lap	4 vs. 6 (NS)	NS
Maartense <i>et al.</i> , 2004 <sup>6</sup>	RCT HAL (30) vs. open (30)	Longer for HAL	HAL (27%) Open (23%)	10 vs. 11 (NS)	NS
Larson <i>et al.</i> , 2005 <sup>7</sup>	Case-matched lap (33) vs. open (33)	NR	All Lap, majority open	NR	NS
Larson <i>et al.</i> , 2006 <sup>8</sup>	Case-matched lap + HAL (100) vs. open (200)	Longer for Lap + HAL	NR	4 vs. 7 ( $P < 0.05$ )	NS
Zhang <i>et al.</i> , 2007 <sup>9</sup>	Case-matched lap (21) vs. open (25)	Longer for Lap	Number not reported	9 vs. 11 ( $P < 0.05$ )	NS

LOS = length of stay; OR = operating room; Lap = laparoscopic-assisted; HAL = hand-assisted laparoscopic surgery; RCT = randomized, controlled trial, NR = not reported; NS = not significant.

postoperative care pathway regarding timing of removal of drains. Also, unlike the present study, Larson's series was based on cases that were primarily diverted at RPC. Additionally, the proportion of patients who underwent endoanal mucosectomy vs. double-stapled anastomosis was not specified by the authors.<sup>8</sup>

In this study, the rates of anastomotic leakage were not statistically different between the one-stage laparoscopically assisted and open groups. The overall incidence of anastomotic leak was 7.3 percent; there was a significant difference between the laparoscopically assisted (8 percent) and open (7.1 percent) groups. This compares favorably with other series, reporting a 5 to 15 percent incidence of anastomotic leak.<sup>12,14-19</sup>

The results of the current study must be tempered by the nonrandomized nature and inherent bias of case selection. Patients who underwent laparoscopically assisted surgery were more likely to be younger females with a shorter duration of illness than those treated with open surgery. Laparoscopically assisted RPC was not offered to all patients. There was a tendency to choose thinner patients for laparoscopically assisted surgery because higher BMI is associated with increased conversion rates and greater risk of major postoperative complications.<sup>12</sup> It is possible that a similar, randomized study might yield different results.

## CONCLUSIONS

Our study compared laparoscopic to open RPC in a large group of patients where the intent was to complete the surgery in one stage. There was no significant difference

in the rates of postoperative complications or patients who required fecal diversion. Although operative times are longer, blood loss appears to be reduced in the laparoscopic group. It appears that the laparoscopic approach to one-stage restorative proctocolectomy provides a safe alternative to patients requiring this procedure.

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