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Original Article

A Case-matched Comparative Study of Laparoscopic and Open Total Proctocolectomy for Ulcerative Colitis

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The aim of this single-institution, retrospective, observational case-control study was to evaluate the safety and feasibility of laparoscopic proctocolectomy (PC) for ulcerative colitis (UC), by comparing it with a case-control series of open PC. Twenty UC patients who underwent laparoscopic PC were retrospectively compared with the open PC group of 12 patients matched for age, sex, and urgency of the operation. In the laparoscopic PC group, the operative time was significantly longer, but the amount of blood loss was significantly smaller. The open PC patients underwent an intraoperative blood transfusion significantly more often, and the serum C-reactive protein level on the first postoperative day was significantly higher in the open PC group. In the laparoscopic PC group, the rate of severe postoperative morbidities, grades 3 and 4 on the Clavien-Dindo classification, was significantly lower, and the median length of hospital stay was significantly shorter. Laparoscopic PC for patients with UC showed superior perioperative outcomes to open PC, except for longer operative time.

Key words: laparoscopic surgery, total proctocolectomy, open proctocolectomy, ulcerative colitis, case-matched study

Ulcerative colitis (UC) is a much more common bowel disease in Western countries than in Asian countries, including Japan [1, 2]. Although the prevalence of UC in Western countries has been reported to have reached a plateau [1], it continues to increase rapidly in Asian countries [3]. The surgical indications for UC are fulminant status, including toxic dilation of the colon, perforation, and severe bleeding, refractory to medical treatment, and carcinogenesis arising from colitis. Treatment with immunosuppressive drugs, including infliximab (an anti-tumor necrosis factor (TNF) antibody), for UC has been reported to be effective for patients with severe active and controversial treatment-resistant UC, reducing the need for surgical treatment [4–6]. The rate of patients with UC who can avoid surgical treatment is increasing, but surgical treatment remains especially necessary for UC patients who are refractory to medical treatment, including infliximab, and those who develop cancer.

Laparoscopic surgery for colorectal cancers began

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in 1991 [7] and has rapidly spread as a minimally invasive procedure since then. Some large-scale randomized controlled trials (RCTs) revealed comparable or superior short- and long-term outcomes of laparoscopic surgery to those of open surgery for colorectal cancers [8–12]. With regard to UC, laparoscopic PC was first reported as a novel minimally invasive procedure for UC in 1992 [13], but it has spread only relatively slowly due to its complicated technique. Some comparative studies of open and laparoscopic PC for UC have been published, and they indicated that the benefits of laparoscopic surgery for UC compared with those of open PC remain controversial [14–23].

The aim of the present study was to evaluate the safety, feasibility, and short-term outcomes of laparoscopic PC for UC by comparing it with a case-control series of open PC.

Materials and Methods

This study was a single-institution, retrospective, observational case-control analysis of laparoscopic PC and open PC for UC. In our institution, 58 patients with UC, including 7 cases with colitis-associated cancers, underwent PC between January 2004 and February 2014. Of these 58 cases, 14 underwent laparoscopic PC, and 44 cases underwent open PC. Twelve of the 14 patients who underwent laparoscopic UC were compared with 12 of the 44 control open PC patients matched in a one-to-one fashion by age (±4 years), sex, and operative management (elective or emergent operation).

The cases of 2 patients who underwent laparoscopic PC were excluded from the study because matched open UC cases were not available. The other parameters that were examined were the American Society of Anesthesiologists' Physical Status (ASA-PS) classification, the body mass index (BMI), history of laparotomy, prior medical treatment for UC, development of carcinoma, anastomosis of the ileum and anus or anal canal, length of operation, amount of blood loss, conversion to laparotomy, intraoperative blood transfusion, postoperative intensive care unit (ICU) stay, serum white blood cell (WBC) count and C-reactive protein (CRP) level on the first postoperative day (POD), length of hospital stay, and postoperative mortality and morbidity.

In terms of prior medical treatment, infliximab was included as immunosuppressive treatment, and morbidity was graded on the Clavien-Dindo classification [24]. Although the hospital discharge could be influenced by many subjective factors, the criteria of the discharge was generally as follows; a normal diet was tolerated, stool frequency was acceptable, complications were improved and pain was controlled only with oral drugs.

Our standard techniques of open and laparoscopic PC were as follows. The patient was fixed on the operating table in the lithotomy position. For each laparoscopic PC, pneumoperitoneum was achieved, and access to the abdomen was gained using 12–mm and 5–mm trocars at the umbilicus, right upper abdomen, right lower abdomen, left upper abdomen, and left lower abdomen. For each open PC, the abdomen was opened through a median incision. After the left colon and splenic flexure were mobilized with preservation of the inferior mesenteric plexus and superior hypogastric plexus, ligation of the inferior mesenteric vessels was performed. For the laparoscopic PC, medial to lateral retroperitoneal dissection of the mesocolon and early division of the inferior mesenteric vessels, the so-called laparoscopic medial-to-lateral approach, was performed. After that, the rectum was mobilized to the level of the levator muscle with preservation of bilateral hypogastric nerves and the pelvic plexus. Successively, the right colon and hepatic flexure were similarly mobilized to the left colon, and the mesentery was cut with ligation of the feeding vessels of the right colon, including the ileocolic vessels, the accessory right colic vein, the right colic vessels, and the middle colic vessels. For cases with locally advanced colorectal cancers, complete dissection of regional lymph nodes, *i.e.*, D3 lymph node dissection in the Japanese classification of colorectal carcinoma [25], was performed. After mobilization of the colorectum and ligation of the feeding vessels, dissection of the tract of the anal side was performed.

For cases with ileo-anal anastomosis (IAA), the intersphincteric plane between the puborectalis and the internal sphincter was dissected as caudal as possible from the abdominal side. After the anal canal was retracted, the anal canal mucosa was circumferentially incised and closed, and it was then irrigated by povidone iodine and saline. The endoanal resection led

to the dissection of the abdominal side, and the specimen was removed through a small circular incision at the stoma site at the right lower abdomen for laparoscopic cases. After the pelvic cavity and anal canal were washed, a J-pouch was constructed for anastomosis using the ileum which was mostly free from tension, and then a J-pouch-anal anastomosis was performed by 4–0 absorbable vertical mattress sutures. A drain was placed at the pelvis, and a diverting ileostoma was made.

For cases with ileo-anal canal anastomosis (IACA), the anal canal was transected via an abdominal approach using a linear stapler, and the specimen was removed. A J-pouch was constructed, and a J-pouch-anal canal anastomosis was achieved using a circular stapler with double stapling technique. A diverting ileostoma was created, and a drain was placed at the pelvis.

In cases without anastomosis, 2 types of procedures were used; an anal sphincter-preserving (SP) procedure and a non-anal sphincter-preserving (non-SP) procedure. For the SP cases, after mobilization of the rectum, the lower rectum or anal canal was transected, the specimen was removed, and an ileostoma was created after washing the pelvis and placing a drain. For the non-SP cases, after the terminal ileum was cut on the abdominal approach, the perineal approach was started. After the anus was closed, the anococcygeal ligament and levator muscle were cut. The perineal approach circumferentially led to the pelvic cavity, and the specimen was removed through the perineal wound as for abdominal perineal resection for rectal cancers [26].

After the perineal wound was closed by primary suture, a drain was placed at the pelvic cavity, and a permanent ileostoma was fashioned. In the laparoscopic PC cases, no abdominal incisions were made except for the port sites and a stoma site. Laparoscopic PC was converted to laparotomy if open techniques were needed to manage unexpected intraoperative difficulties, regardless of the size of incision.

The selection criteria for reconstruction after PC were basically as follows. IAA was generally selected for the patients with UC, and IACA was selected mainly for the older patients to preserve postoperative anal sphincter function. Patients who did not hope for defecation through their anus selected SP. For patients without a definitive preoperative diagnosis of UC in whom Crohn's disease may have been possible, SP was also selected, and removal of the residual rectum and anal canal and anastomosis were performed later after the definitive diagnosis of UC was made by examination of the resected specimen. Non-SP was selected. Cases with lower rectal cancers selected non-SP. In this study, the reconstructive procedures were classified into 2 categories, those with anastomosis (IAA and IACA) and those without (SP and non-SP).

At our institution, laparoscopic PC was started in 2011, and now laparoscopic PC is usually selected except for cases of fulminant UC, with features such as toxic dilation of the colon, perforation and severe bleeding; advanced colitis-associated cancers (T4); severe obesity (BMI $> 35\,kg/m^2$), and cases in which consent for laparoscopic surgery was not provided.

All cases were evaluated by colonoscopy performed by specialists in gastroenterology, and the patients who were preoperatively diagnosed as having carcinoma or dysplasia underwent computed tomography for metastases. Three staff surgeons who had experience with at least 300 cases of open colorectal surgeries performed the open PCs, and one staff surgeon who had experience with more than 150 cases of laparoscopic colorectal surgeries performed the laparoscopic PCs.

This study was approved by the institutional review board of the Okayama University Hospital.

All statistical analyses were performed using the SPSS ver. 20.0 software program (SPSS, Chicago, IL, USA). Categorical variables were compared by Fisher's exact test, and independent continuous subgroups were compared by the Mann-Whitney U-test. P-values < 0.05 were considered significant.

Results

The clinical characteristics of the patients in this case-control study are shown in Table 1. There were no significant differences between the laparoscopic PC group (n=12) and the open PC group (n=12) in patient background characteristics, including ASA-PS, BMI, prior treatments, and the development of carcinoma.

Intra- and postoperative results are presented in Table 2. All cases analyzed underwent elective surgeries, and there were no conversions to laparotomy in the laparoscopic PC group. With respect to recon-

Table 1 Characteristics of patients with ulcerative colitis

Variable	Laparoscopic PC (n = 12)	Open PC (n = 12)	*P*-value
Age (years)			
Median (range)	39.5 (17–79)	36.5 (14–78)	0.799
Sex			
Male/Female	6/6	6/6	1.000
ASA-PS			
1/2, 3	8/4	9/3	1.000
BMI (kg/m^2)			
Median (range)	20.3 (18.0–24.1)	20.0 (13.7–26.3)	0.932
Prior abdominal operation			
Present/Absent	1/11	1/11	1.000
Prior steroid treatment			
Present/Absent	10/2	11/1	1.000
Prior immunosuppressive treatment			
Present/Absent	8/4	6/6	0.680
Carcinoma			
Present/Absent	3/9	0/12	0.217

PC, proctocolectomy; ASA-PS, American Society of Anesthesiologists' Physical Status classification; BMI, body mass index.

Table 2 Intraoperative and postoperative results

Variable	Laparoscopic PC (n = 12)	Open PC (n = 12)	*P*-value
Operative management			
Elective/Emergent	12/0	12/0	1.000
Anastomosis of ileum and anus or anal canal			
Present/Absent	7/5	7/5	1.000
(IACA, IAA/SP, non-SP)	(3, 4/4, 1)	(7, 0/5, 0)	
Length of operation (min)			
Median (range)	415 (258–546)	255 (130–575)	<0.001
Amount of blood loss (mL)			
Median (range)	45 (5–600)	400 (100–6,000)	<0.001
Conversion to laparotomy			
Present/Absent	0/12	NA	NA
Intraoperative blood transfusion			
Present/Absent	1/11	8/4	0.009
Postoperative ICU management			
Present/Absent	4/8	6/6	0.680
WBC count on the 1st POD (/ μL)			
Median (range)	9,160 (5,490–20,590)	9,170 (4,310–21,600)	0.713
CRP level on the 1st POD (mg/dL)			
Median (range)	5.0 (2.0–12.0)	8.1 (2.0–24.0)	0.045
Length of hospital stay (days)			
Median (range)	22.5 (12–35)	32 (17–118)	0.010

PC, proctocolectomy; IACA, ileo-anal canal anastomosis; IAA, ileo-anal anastomosis; SP, sphincter-preserving procedure; NA, not applicable; ICU, intensive care unit; WBC, white blood cell count; POD, postoperative day; CRP, C-reactive protein.

struction after PC, in each group, seven cases underwent anastomosis of the ileum and anus or anal canal, and 5 did not. In the laparoscopic PC group, the operative time was significantly longer, but the amount of blood loss was significantly smaller compared to the open PC group (each $p < 0.001$). The

Open PC group underwent intraoperative blood transfusion significantly more often ($p = 0.009$), and the serum CRP level on the first postoperative day was significantly higher in the open PC group ($p = 0.045$). The median length of postoperative stay in the laparoscopic PC group was 22.5 days, which was significantly shorter than that in the open PC group (32 days; $p = 0.010$).

Mortality and morbidity graded on the Clavien-Dindo classification are shown in Table 3. There was no perioperative mortality in either group. The total postoperative morbidity rate was not significantly different between the 2 groups ($p = 0.089$), but severe postoperative morbidities, *i.e.*, grades 3 and 4 on the Clavien-Dindo classification, were significantly less frequent in the laparoscopic PC group than in the open PC group ($p = 0.005$). One patient in the open PC group was re-admitted within 30 days of the PC because of intestinal obstruction.

With respect to long-term outcomes, all 24 of the patients were alive as of this writing (median follow-up 20.4 months, range 3.0–106.9 months), and all three colitis-associated UC cases treated by laparoscopic PC had no recurrence. Two patients, including one laparoscopic IACA and one open IACA, had slight pouchitis after discharge.

Discussion

Laparoscopic surgery for colorectal cancers was first reported in 1991 [7], and its efficacy and safety have been sufficiently proven by some large-scale RCTs [8–12]. Laparoscopic PC for UC was first reported in 1992 [13], but it has not spread widely because of the difficulty of the procedure and the complicated clinical aspects of UC as an inflammatory disease. Due to the accumulation of experience with laparoscopic colorectal surgery and the reduction of uncontrollable conditions due to progress in medical therapies for UC [4–6], the use of laparoscopic PC for UC has gradually increased. Some comparative studies of open PC and laparoscopic PC, including a small number of RCTs [20, 22], have been reported. Most of the comparative studies simultaneously exam-

Table 3 Mortality and morbidity (Clavien-Dindo grade)

Variable	Laparoscopic PC (n = 12)	Open PC (n = 12)	*P*-value
Mortality	0	0	1.000
Morbidity			
Grade 1, 2			
Stoma site infection	0	1	
Intrapelvic abscess	1	0	
Intravenous catheter infection	1	2	
Enteritis	0	1	
Cystitis	1	0	
Intraabdominal bleeding	1	0	
Duodenal ulcer	0	1	
Venous thrombosis	1	1	
Liver dysfunction			
Grade 3, 4			
Intestinal obstruction	0	1	
Leakage	0	1	
Wound infection	0	3	
Stoma site infection	0	1	
Intrapelvic abscess	0	2	
Intestinal perforation	0	1	
Total (number of patients)			
Grade 1, 2, 3, 4	5	10	0.089
Grade 3, 4	0	7	0.005
Re-admission within 30 days	0	1	1.000

PC, proctocolectomy.

ined UC and familial adenomatous polyposis (FAP) and originated from Western countries. Moreover, most of them analyzed open PC versus hand-assisted laparoscopic PC alone or open versus a combination of hand-assisted and completely laparoscopic PC. There were few comparative studies of open PC versus completely laparoscopic PC for UC alone.

In one RCT published in 2004, comparing hand-assisted laparoscopic PC and open PC for UC and FAP, laparoscopic PC was observed to be as safe as open PC, but the laparoscopic PC group did not show superior short-term and middle-term outcomes, including amount of blood loss, morphine requirement, length of hospital stay, morbidity, and postoperative quality of life, to the open PC group, and the laparoscopic PC group had worse outcomes in terms of operative time and treatment costs [20]. Another RCT published in 2013, comparing completely laparoscopic PC and open PC for UC and FAP, also found that the only superior outcome in the laparoscopic group was cosmesis [22]. The problems of these two RCTs were that they were small-scale, with only 60 and 42 cases, respectively, and the later trial was stopped prematurely due to difficulty with recruitment [22].

Therefore, there are no appropriate large-scale, prospective, RCTs of laparoscopic surgeries for UC as there are for colorectal cancers. With respect to retrospective studies, one large-scale, case-matched trial, comparing 100 hand-assisted and completely laparoscopic PC cases versus 200 matched open PC cases for UC and FAP, was published, and it showed that laparoscopic PC was equivalently safe and feasible, with short-term recovery outcomes that were superior to those of the open PC group [23]. There have been some other relatively small-scale, retrospective, comparative studies for laparoscopic and open PC for UC, and their outcomes are controversial [14–19, 21].

In the present study, the short-term outcomes of the 12 completely laparoscopic PC and the 12 open PC cases matched by age, sex, and operative management (emergent or elective surgery) only for UC were compared. Other patient background characteristics, including ASA-PS, BMI, and prior medical therapy for UC, were not significantly different between the 2 groups. All 24 cases were matched for elective surgery, and the rates of anastomosis of the ileum and anus or anal canal were not different.

All of the patients in the laparoscopic PC group avoided conversion to laparotomy, and the laparoscopic PC group showed significantly better perioperative outcomes, including the amount of blood loss, intraoperative blood transfusion, postoperative severe morbidities, and length of hospital stay, compared to the open PC group. From the cosmetic perspective, the laparoscopic PC group had much better cosmetic outcomes, since the laparoscopic PC procedure involved no abdominal incisions, except for port sites and a stoma site.

Although the operative time of the present laparoscopic PC group was significantly longer than that of the open PC group, in cases of elective surgery, a longer operative time is permitted to a certain degree, if the operative methods have other benefits. The results of the present study showed several points of superiority of laparoscopic surgery for UC, but this study was a small-scale, single-center, retrospective trial, and reconstruction procedures after PC could not be completely matched between the 2 groups. In addition, the laparoscopic PCs were performed by only one surgeon. This is a limitation of the present study, since the number of UC patients in Japan has been smaller than in Western countries, and the conditions of UC patients are quite variable. In regard to learning the techniques of laparoscopic PC, laparoscopic colorectal surgery, including the right-sided colon, left-sided colon and rectum, and the pouch procedure should be previously experienced.

In conclusion, we observed that laparoscopic PC for UC is a safe and feasible procedure, and postoperative surgical outcomes will be superior compared to open PC. To test these results, further evidence is needed, preferably from multicenter, prospective trials.

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