

## ORIGINAL ARTICLE

## Feasibility and safety of laparoscopic total proctocolectomy with ileal pouch-anal anastomosis for severe ulcerative colitis

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### Abstract

**Introduction:** The laparoscopic approach is accepted as a treatment option for patients with ulcerative colitis (UC) who are otherwise in good health. However, its application for patients with severe UC remains controversial. The purpose of this study was to evaluate the feasibility of the laparoscopic approach for severe UC cases. Short- and long-term clinical outcomes after laparoscopic total proctocolectomy with ileal pouch-anal anastomosis were compared between severe and mild-to-intermediate UC patients.

**Methods:** Cases treated between March 2002 and September 2010 were retrieved retrospectively from the database of Kyoto Medical Center and Kyoto University Hospital. Intraoperative complications and short- and long-term clinical outcomes were compared.

**Results:** A total of 31 patients underwent laparoscopic total proctocolectomy with ileal pouch-anal anastomosis. A comparison of short- and long-term clinical outcomes after one- or two-stage laparoscopic ileal pouch-anal anastomosis between severe ( $n = 7$ ) and mild-to-intermediate ( $n = 21$ ) UC patients revealed no significant differences. The proportion of patients with restoration of intestinal continuity did not differ between the groups (severe: 86%, mild to intermediate: 95%;  $P = 0.69$ ).

**Conclusion:** The present findings suggest that laparoscopic total proctocolectomy with ileal pouch-anal anastomosis for severe UC patients could be a good alternative approach when performed by an experienced hand.

### Introduction

Ulcerative colitis (UC), an inflammatory disorder of the colon and rectum, has a reported incidence of 8–10 cases per 100 000 in Japan, and the prevalence has increased tenfold in the last 25 years (1). The natural course of UC varies depending on the site and the extent of bowel inflammation. While some patients remain relatively asymptomatic, others present with disease manifestations requiring surgical intervention. The surgical choice varies depending on the severity of disease and can range from open subtotal colectomy (STC) to laparoscopic total

proctocolectomy with ileal pouch-anal anastomosis (LAP-IPAA). For patients in good health otherwise, the laparoscopic approach is a treatment option available for UC in clinical settings. However, laparoscopy for patients with severe UC or patients requiring emergency surgery remains controversial (2).

At our institution, we perform laparoscopic surgery for most UC patients irrespective of the severity of the disease, although patients are not treated laparoscopically when presenting with fulminant UC, perforated colitis, massive bleeding, or toxic megacolon. Our laparoscopic procedure seems to be technically fea-

sible for cases of severe UC, but it is not clear whether patients with severe UC achieve clinical outcomes similar to patients with mild or intermediate UC.

The purpose of this study was to evaluate the feasibility of our laparoscopic approach for the treatment of severe UC by comparing short- and long-term clinical outcomes after LAP-IPAA for severe and mild-to-intermediate UC.

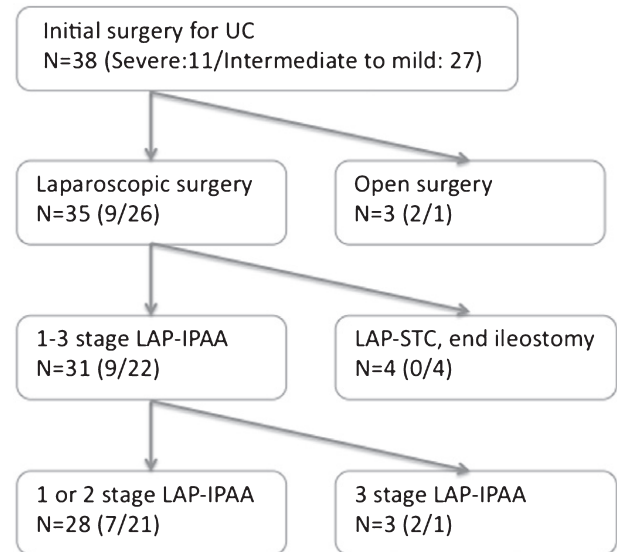
## Methods and Materials

Cases of UC treated between March 2002 and September 2010 were retrospectively retrieved from the UC database of Kyoto Medical Center (Kyoto, Japan) and Kyoto University Hospital (Kyoto, Japan). This database includes patient demographic factors (age, sex, height, body weight, and medical history), duration of disease, indication for surgery, disease severity, preoperative laboratory data, preoperative medical treatment (including use and doses of steroids equivalent to prednisolone and of immunosuppressive agents), operative factors (date, procedures, time, estimated blood loss, conversion to open surgery, and intraoperative complications), and short- and long-term postoperative complications. In total, 38 consecutive patients who underwent initial surgical procedures for UC were identified. Two patients with toxic megacolon and one patient with severe peritoneal dissemination of colon cancer were treated with a conventional open method. The remaining 35 patients underwent laparoscopic surgery, and four patients underwent laparoscopic-STC (LAP-STC) and permanent ileostomy creation for technical reasons or in accordance with the patient's wish. Three patients with restricted activities of daily living underwent LAP-STC, with the subsequent IPAA performed laparoscopically (three-stage LAP-IPAA). Thus, 10 patients, including 4 with severe UC, were excluded from this study, leaving a study cohort of 28 patients who underwent one- or two-stage LAP-IPAA (Figure 1).

Diagnosis of severe UC was based on modification of Truelove and Witts' criteria: (i) >6 stools/day; (ii) bloody diarrhea; (iii) fever >37.5°C; (iv) heart rate >90 bpm; (v) hemoglobin >10 g/dL; and (vi) erythrocyte sedimentation rate >30 mm/h. When the first two criteria apply, either criterion three or four applies. If four of the six criteria apply, UC is diagnosed as severe (3,4).

Statistical analysis was performed using SPSS v. 11J (SPSS Japan Inc., Tokyo, Japan). Fisher's exact test, the  $\chi^2$  test, and the Mann-Whitney *U*-test as well as multiple logistic regression analysis were used for data analyses.  $P < 0.05$  was considered statistically significant.

This study was approved by the institutional review boards of Kyoto University and Kyoto Medical Center.



**Figure 1** Surgical approaches for cases of ulcerative colitis (UC) studied. LAP-IPAA, laparoscopic total proctocolectomy with ileal pouch-anal anastomosis; LAP-STC, laparoscopic-subtotal colectomy.

## Surgical technique

Our LAP-IPAA procedure has been described previously (5). Briefly, patients are placed in a modified lithotomy position, and we use five ports as previously described by Kim and Milsom (6). A pneumoperitoneum of 8 mmHg is maintained. With the patient in a deep Trendelenburg position, the small bowel mesentery is first dissected from the ligament of Treitz to the cecum, and then the ascending colon mesentery is mobilized through the same dissection plane. The operative field is then shifted to the pelvis, with the patient in the same table position. The posterior side of the rectum is dissected between the mesorectum and the hypogastric nerve fascia so that the hypogastric nerves and pelvic plexus can be identified and preserved (7). The anterior dissecting plane is between Denonvilliers' fascia and the rectum (8). After the rectum is circumferentially dissected down to the pelvic floor, the table position is rotated to the reverse Trendelenburg position. The omentum is divided, and the hepatic and splenic flexures are mobilized. The left colonic vessels are divided, and the remaining lateral attachment of the descending and ascending colon is divided. The ileocecal vessels are preserved to maintain an adequate blood supply to the ileal pouch. Transanal rectal mucosectomy is performed with a modification of Kusunoki's method (9). With the patient in the Lloyd-Davies position, the circumferential mucosectomy is started at the lower margin of the dentate line. The mucosa is stripped to approximately 3–4 cm from the dentate line above the levator ani muscle, and the circum-

**Table 1** Patients' characteristics

	Severe UC (n = 7)	Mild-to-intermediate UC (n = 21)	P-value
Median age, years (range)	34 (16–64)	35 (16–66)	0.91
Sex (men: women)	4:3	13:8	0.58
Median BMI (range)	17.7 (16.1–19.5)	19.5 (13.1–23.6)	0.27
Median disease duration, year (range)	8 (4–9)	7 (0–30)	0.83
Indications for surgery (n)			
Acute flare unresponsive to medical treatment	6 (86%)	0 (0%)	–
Medical intractability	0 (0%)	14 (67%)	–
Risk of malignancy	0 (0%)	6 (29%)	–
Bleeding	1 (14%)	0 (0%)	–
Rectal stricture	0 (0%)	1 (5%)	–
Total steroid dose <sup>†</sup> >10 g (n)	3 (43%)	13 (61%)	0.32
Preoperative steroid dose (mg/day)	15 (0–80)	5 (0–80)	0.27
Preoperative steroid dose >10 mg/day (n)	4 (57%)	9 (43%)	0.41
Immunosuppressive therapy (n)	4 (57%)	9 (43%)	0.41
Emergency (n)	2 (29%)	1 (5%)	0.001
Median WBC (μL)	9 900 (6 600–15 500)	5 600 (3 600–11 700)	0.004
Median Hb. (g/dL)	9.7 (7.0–12.9)	10.2 (7.5–15.3)	0.32
Median CRP (mg/dL)	1.7 (0.0–4.8)	0.1 (0.0–13.0)	0.042
Median Alb. (g/dL)	2.8 (2.2–3.6)	3.6 (2.0–4.7)	0.01

<sup>†</sup>Equivalent to prednisolone dose. Alb., albumin; CRP, C-reactive protein; Hb., hemoglobin; UC, ulcerative colitis; WBC, white blood cell count.

ferential muscular layer of the rectum is easily transected. After rectal mobilization and transection, the right lower quadrant trocar site is enlarged to exteriorize the bowel. The terminal ileum is then transected and a 15-cm ileal J-pouch is constructed. After pneumoperitoneum has been established, the ileal pouch is delivered to the anus under laparoscopic view, and a hand-sewn IPAA is created. Finally, a temporal loop ileostomy is performed in cases requiring two-stage procedures.

## Results

### Demographics

A total of 31 patients underwent LAP-IPAA for UC (stage 1–3). Among them, three severely wasted patients underwent three-stage LAP-IPAA. Thus, a comparison of clinical outcomes between severe and mild-to-intermediate UC groups was made on 28 patients who underwent one- or two-stage LAP-IPAA. Seven patients were classified as having severe UC and the remaining 21 patients as having mild-to-intermediate UC. There were no significant differences with respect to age, sex, disease duration, or preoperative administration of immunosuppressive agents between the two groups (Table 1). Indications for surgery included acute flare unresponsive to medical treatment, medical intractability, risk of malignancy, bleeding, and rectal stricture. Medical intractability was the most common indication for surgery in the mild-to-intermediate UC group, followed by risk of malignancy. All patients, except those with cancer or dysplasia,

received steroidal or immunosuppressive management for more than 12 months. Patients in the severe UC group tended to use higher prednisolone-equivalent doses of steroids preoperatively (severe UC, 15 mg/day; mild-to-intermediate UC, 5 mg/day;  $P = 0.272$ ). Emergency surgery was needed in two patients in the severe UC group and one patient in the mild-to-intermediate UC group (29% versus 5%, respectively;  $P = 0.001$ ).

Two patients in the mild-to-intermediate UC group underwent one-stage LAP-IPAA and the remaining 26 patients underwent two-stage LAP-IPAA.

### Surgical outcomes

There were no significant differences between the groups with regard to operative parameters, including median operative time (severe UC, 392 min; mild-to-intermediate UC, 440 min) and estimated blood loss (severe UC, 80 mL; mild-to-intermediate UC, 140 mL (Table 2)). There were no intraoperative complications, such as bowel perforation or massive bleeding, and no conversions to open surgery in either group.

### Short-term complications

The proportion of patients suffering overall postoperative complications (Common Terminology Criteria for Adverse Events v4.0  $\geq$ Grade 1) was similar between the groups (severe UC,  $n = 3$  [43%]; mild-to-intermediate UC,  $n = 12$  [57%],  $P = 0.41$ ) (Table 3). One patient with severe UC developed an anastomotic leak and recovered after conservative treatment.

**Table 2** Intraoperative parameters

	Severe UC (n = 7)	Intermediate to mild UC (n = 21)	P-value
Median operative time (min)	392 (365–523)	440 (359–618)	0.22
Median estimated blood loss (mL)	80 (15–530)	140 (10–580)	0.40
Conversion to open surgery (n)	0	0	
Intraoperative complication (n)	0	0	

UC, ulcerative colitis.

**Table 3** Short-term outcomes

	Severe UC (n = 7)	Intermediate to mild UC (n = 21)	P-value
Patients with short-term complications <sup>†</sup> (n)	3 (43%)	12 (57%)	0.41
Small bowel obstruction (n)	2 (29%)	10 (48%)	0.33
Anastomotic leakage (n)	1 (14%)	0	0.25
Pouchitis (n)	0	0	–
Wound infection (n)	0	5 (24%)	0.20
Intestinal perforation (n)	0	1 (5%)	0.75
Venous thromboembolism (n)	0	0	–
Major complications <sup>‡</sup> (n)	2 (29%)	3 (14%)	0.36
Re-laparotomy (n)	0	3 (14%)	0.40
Mortality (n)	0	0	–

<sup>†</sup>Common Terminology Criteria for Adverse Events v4.0 ≥ Grade 1.

<sup>‡</sup>Common Terminology Criteria for Adverse Events v4.0 ≥ Grade 3.

UC, ulcerative colitis.

**Table 4** Short-term major complications

	Cases with short-term major complications (n = 5)	Cases with long-term major complications (n = 23)	P-value
Median age, year (range)	29 (27–58)	35 (16–66)	0.92
Sex (men: women)	4:1	13:10	0.32
Median BMI (range)	17.8 (17.0–20.2)	19.0 (13.1–23.6)	0.81
Median disease duration, year (range)	8 (3–22)	7 (0–30)	0.90
Total steroid dose <sup>†</sup> >10 g (n)	3 (60%)	13 (57%)	0.64
Median preoperative steroid dose, mg/day (range)	20.0 (15.0–80.0)	2.5 (0.0–80.0)	0.06
Preoperative steroid dose >10 mg/day (n)	5 (100%)	8 (35%)	0.01
Immunosuppressive therapy (n)	2 (40%)	11 (48%)	0.57
Emergency (n)	2 (40%)	4 (17%)	0.28
Severe UC (n)	2 (40%)	5 (22%)	0.36
Median operative time, min (range)	386 (359–473)	440 (361–618)	0.10
Median estimated blood loss, mL (range)	120 (15–170)	145 (10–580)	0.41
Median WBC (μL)	8300 (5100–15 500)	5800 (3600–11 700)	0.19
Median Hb. (g/dL)	11.7 (10.1–15.3)	9.7 (7.0–13.9)	0.04
Median CRP (mg/dL)	0.1 (0.0–2.8)	0.1 (0.0–13)	0.48
Median Alb. (g/dL)	3.4 (2.8–4.4)	3.6 (2.0–4.7)	0.72

<sup>†</sup>Equivalent to prednisolone dose. Alb., albumin; CRP, C-reactive protein; Hb., hemoglobin; UC, ulcerative colitis; WBC, white blood cell count.

Short-term major complications (Common Terminology Criteria for Adverse Events v4.0 ≥ Grade 3) occurred in five patients, but there were no significant differences in the incidences between the groups (severe UC, *n* = 2 [29%]; mild-to-intermediate UC, *n* = 3 [14%], *P* = 0.36) (Table 3). Preoperative steroid dose was significantly associated with short-term major complications (>10 mg/day, *n* = 5 [38%]; <10 mg/day, *n* = 8 [35%], *P* = 0.001)

(Table 4), which did not reach statistical significance on multiple logistic regression analysis (data not shown). No mortality occurred in either group.

#### Long-term complications

Median follow-up for all patients was 48 months (range, 4–105 months). There were no significant differences in overall long-term complication rates between the two

**Table 5** Long-term outcomes

	Severe UC ( <i>n</i> = 7)	Mild-to-intermediate UC ( <i>n</i> = 21)	<i>P</i> -value
Patients with long-term complications <sup>†</sup> ( <i>n</i> )	2 (29%)	6 (29%)	0.69
Pouchitis ( <i>n</i> )	0	5 (24%)	0.20
Perianal abscess ( <i>n</i> )	2 (29%)	0	0.056
Small bowel obstruction ( <i>n</i> )	0	2 (10%)	0.55
Portal thrombosis ( <i>n</i> )	0	1 (5%)	0.75
Stomal hernia ( <i>n</i> )	0	0	–
Incisional hernia ( <i>n</i> )	0	1 (5%)	0.75
Duodenitis ( <i>n</i> )	0	1 (5%)	0.75
Patients with restoration of intestinal continuity ( <i>n</i> )	6 (86%)	20 (95%)	0.69

<sup>†</sup>Equivalent to prednisolone dose.

UC, ulcerative colitis.

**Table 6** Demographic data of patients developing SBO before ileostomy closure

No	Age (years)/sex	BMI	Disease term (years)	Emergency or elective surgery	Operative time (min)	Blood loss (mL)	Severity	Prednisolone (mg)	Cause of SBO	Treatment for SBO
1	23/M	16.8	8	Elective	505	70	Mild/int.	0	Unknown	–
2	36/M	21.2	10	Elective	570	135	Mild/int.	15	Unknown	–
3	28/M	17.7	8	Emergency	368	15	Severe	15	Kink	Long tube insertion
4	17/M	22.8	4	Elective	373	10	Mild/int.	80	Kink	Catheter insertion
5	16/M	16.1	4	Emergency	392	80	Severe	0	Kink	Catheter insertion
6	27/M	20.2	3	Elective	417	40	Mild/int.	15	Kink	Stoma closure
7	58/W	17.8	22	Elective	473	120	Mild/int.	20	Kink	Stoma closure
8	58/M	21.5	0	Elective	566	110	Mild/int.	0	Unknown	–
9	29/M	19.8	3	Elective	359	170	Mild/int.	20	Kink	Refashioning of ileostomy
10	35/M	14.0	7	Elective	431	250	Mild/int.	20	Kink	Catheter insertion
11	19/W	13.1	4	Elective	428	100	Mild/int.	0	Unknown	–
12	49/W	14.8	9	Elective	440	70	Mild/int.	5	Kink	Catheter insertion

M, man; Mild/int., mild-to-intermediate; SBO, Small bowel obstruction; W, woman.

groups (severe UC, *n* = 2 [29%]; mild-to-intermediate UC, *n* = 6 [29%], *P* = 0.69) (Table 5). Perianal abscess occurred in two patients (29%) in the severe UC group. Five patients in the mild-to-intermediate UC group developed mild pouchitis. The proportion of patients with restoration of intestinal continuity did not differ between the groups (severe UC, *n* = 6 [86%]; mild-to-intermediate UC, *n* = 20 [95%], *P* = 0.69).

### Small bowel obstruction

Among 26 patients with two-stage LAP-IPAA, 13 developed small bowel obstruction (SBO) before or after ileostomy closure. The incidence of SBO differed substantially before and after ileostomy closure (before, *n* = 12 [42%]; after, *n* = 2 [7%]) (Tables 3,5). One patient developed SBO before and after ileostomy closure. The major cause of SBO before ileostomy closure seemed to be a kink or twist of the ileostomy just proximal to the ileostomy site, and SBO was temporarily resolved after

catheter insertion into the oral side of ileostomy. Two patients, however, had refractory obstruction and needed to undergo a stoma closure earlier than planned. One developed perforation just proximal to the ileostomy site and underwent emergency laparotomy (Table 6). The incidence of SBO before or after ileostomy closure did not differ between the two groups (severe UC, *n* = 2 [29%]; mild-to-intermediate UC, *n* = 10 [48%], *P* = 0.33) (Table 3). In addition, no factors were associated with an increased risk of SBO (data not shown).

### Discussion

Although the role of the laparoscopic technique in the treatment of UC remains controversial because of its complex nature and limited short-term benefits, a subset of patients are thought to be good candidates for laparoscopic approach, as most of the patients with UC are young. Also, many may prefer the laparoscopic approach

to the open approach in hope of potential benefits of minimal invasiveness (10–21). With advances in technology and increased experience with laparoscopic surgery, the feasibility and safety of LAP-IPAA for UC has been reported in the elective setting (2,10–12,22). However, controversy still exists over the standard laparoscopic approach for severe UC because of the technical difficulty of manipulating the fragile bowel to avoid bowel perforation and bleeding (22). Some recent studies have reported the safety of a LAP-STC in severe UC (23–25). Holubar *et al.* showed acceptable overall complication rates and conversion rates of laparoscopic or hand-assisted STC and subsequent IPAA for severe to fulminant UC (23). They concluded that a three-stage laparoscopic approach for patients with severe UC is technically feasible and safe, and it is a reasonable operative strategy that yields short postoperative hospital stays. Pandey *et al.* have also shown the efficacy of a three-stage laparoscopic approach for selected patients in minimizing perioperative complications, but they reached no definitive agreement on the sequence or number of stages to optimize outcome in severe UC (25). The present study focused on the feasibility and safety of two-stage LAP-IPAA for severe UC and showed that there were no significant differences in terms of intraoperative, short-term or long-term outcomes between severe and mild-to-intermediate UC patients. Therefore, our findings indicate that LAP-IPAA is technically feasible and safe for the majority of patients with UC, irrespective of disease severity.

Our current practice is to offer a laparoscopic approach to the majority of our patients, excluding cases of acute colitis complicated by fulminant UC, perforated colitis, massive bleeding, or toxic megacolon. Three-stage LAP-IPAA was recommended for selected patients who were severely malnourished, immunocompromised, and almost confined to bed. In the present series of 38 consecutive patients who underwent initial surgery for UC, 11 had severe UC, 2 with toxic megacolon underwent an open approach, and 2 with reduced activities of daily living underwent three-stage LAP-IPAA. Therefore, 82% of patients with severe UC were treated laparoscopically, including 64% who underwent two-stage LAP-IPAA. We believe that the majority of patients with severe UC may benefit from laparoscopic procedures unless they have an extremely severe condition (e.g. perforation, toxic megacolon).

Some previous studies have reported the preoperative use of steroids to be an independent risk factor for complications after IPAA, and it remains controversial as to whether preoperative infliximab use is a significant risk factor after IPAA (26–29). In this study, there was no significant difference between the severe and mild-to-

intermediate UC groups in terms of short-term major complications. Those patients with such complications tended to use a higher dose of prednisolone-equivalent steroids (more than 10 mg/day), although multivariate analysis did not confirm the association, possibly because of the small sample size. In contrast, the use of preoperative immunosuppressive therapies, such as tacrolimus, azathioprine, and mercaptopurine, did not have an impact on the occurrence of short-term major complications. In the present study, none of the patients had been treated with antitumor necrosis factor antibody (infliximab), as it was not permitted for use in UC in Japan during the study period. Therefore, the medical treatment the study group received before surgery might be different from the standards of care for UC at the present time. Further studies will be needed to determine the effects of steroids, immunosuppressive agents, and infliximab on surgical outcomes after LAP-IPAA.

The incidence of postoperative complications in this study was relatively high compared with several previous studies, and this was due to the high rates of SBO, especially in the short-term period (20–22,30–32). Interestingly, most obstructions occurred before removing the ileostomy, and a similar finding was reported previously (28). The main reason for ileostomy-related SBO seemed to be a kink or twist in the bowel just proximal to the ileostomy site (33). The present findings indicate that SBO remains one of the more common postoperative complications after LAP-IPAA, although the number of severe cases that required emergency surgery was small ( $n = 3$ ). How the oral side of the ileostomy kinked or twisted after LAP-IPAA is unclear and most patients recovered from SBO following the insertion of a catheter through the oral side of the ileostomy in the early postoperative period. This suggests that mechanical obstruction due to a kink, coupled with postoperative paralytic ileus, might cause more severe SBO. Prompt conservative management with bowel rest or decompression by catheter insertion might be helpful for managing SBO in the early postoperative period.

This study had some limitations. First, the severe UC group was small. In order to conclude the feasibility of laparoscopic surgeries, we must accumulate data in more cases of severe UC to achieve adequate statistical power. Second, this study was not a comparison of the outcomes between laparoscopic and open approaches. In assessing the value of laparoscopic surgery for severe UC, the appropriate control group might be the group undergoing open surgery for severe UC. However, the non-inferiority of surgical outcomes demonstrated after laparoscopic surgery in the severe UC group relative to the mild-to-intermediate group might indicate the feasibility of the laparoscopic approach for severe UC patients.

Third, this is a retrospective study and selection bias always remains. In fact, a total of 10 cases were excluded (3 open cases with toxic megacolon and perforation, 4 LAP-STC cases with creation of an end ileostomy, and 3 LAP-STC cases with subsequent laparoscopic proctectomy and IPAA) and among these, 4 patients were classified as having severe UC. Therefore, the patients included in the severe UC group in this study were in relatively good general health otherwise compared to the other severe UC patients. Finally, the results might not be directly applicable to all cases in general practice; the decent results in this study might owe to the great experience of a surgical team that specializes in laparoscopic colorectal surgeries. In this study, the patients with severe UC were in worse condition than those with mild-to-intermediate UC, and great care must be taken to address the difficulties this poses.

The present findings suggest that LAP-IPAA for the treatment of severe UC could be a good alternative approach in experienced hands. Future multicenter prospective trials comparing open and laparoscopic methods in the treatment of severe UC are warranted.

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