ORIGINAL CONTRIBUTION

# Right-Sided Ileostomy on Stoma Outlet Obstruction in Ulcerative Colitis: A Randomized Controlled Trial

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***BACKGROUND:*** Stoma outlet obstruction is a common complication after total proctocolectomy with IPAA for ulcerative colitis, occurring in 20% to 40% of cases. In contrast, the incidence of stoma outlet obstruction after low anterior resection is less than 10%. Because stomas are typically created in the right lower abdomen, we considered that small-bowel torsion and tension might be more pronounced after IPAA. Therefore, we hypothesized that creating a stoma in the left lower abdomen during IPAA could reduce the incidence of stoma outlet obstruction.

***OBJECTIVE:*** To evaluate whether, compared with right-sided placement, left-sided stoma placement reduces the incidence of stoma outlet obstruction.

***DESIGN:*** Single-center, open-label, randomized controlled trial.

***SETTING:*** Conducted at Hyogo Medical University, Japan.

***PATIENTS:*** A total of 181 patients with ulcerative colitis who underwent IPAA with ileostomy between 2018 and 2024 were included.

***INTERVENTIONS:*** Patients were randomly assigned to receive a left-sided (Group L, n = 91) or right-sided (Group R, n = 90) ileostomy.

***MAIN OUTCOME MEASURES:*** Primary outcome includes stoma outlet obstruction incidence. Secondary outcomes include length of hospital stay and reoperation rate. The primary analysis was performed on an intention-to-treat basis.

***RESULTS:*** The incidence of stoma outlet obstruction was significantly lower in Group L (9.8%) than in Group R (31.1%; $p = 0.0004$). A left-sided stoma was an independent protective factor against stoma outlet obstruction (OR 0.24, 95% CI, 0.10–0.56; $p = 0.001$). Stoma outlet obstruction was associated with a longer hospital stay (median: 33 vs 22 days, $p < 0.001$). No significant difference was found in reoperation rates between the L and R groups.

***LIMITATIONS:*** Single-center study; generalizability to other populations is uncertain.

***CONCLUSIONS:*** Left-sided stoma placement significantly reduces the incidence of stoma outlet obstruction in IPAA for ulcerative colitis and may be a preferable approach to improve postoperative outcomes. See **Video Abstract.**

***TRIAL REGISTRATION:*** University Hospital Medical Information Network Clinical Trials Registry: UMIN-CTR 000023750.

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The data sets used and analyzed during the current study are available from the corresponding author on reasonable request.

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## ILEOSTOMÍA DERECHA EN LA OBSTRUCCIÓN DE LA SALIDA DEL ESTOMA EN LA COLITIS ULCEROSA: ENSAYO CONTROLADO ALEATORIO

***ANTECEDENTES:*** La obstrucción de la salida del estoma es una complicación frecuente tras una proctocolectomía

total con anastomosis ileoanal en casos de colitis ulcerosa, que se produce en entre el 20 % y el 40 % de los casos. Por el contrario, la incidencia de obstrucción de la salida del estoma tras una resección anterior baja es inferior al 10 %. Dado que los estomas se crean normalmente en la parte inferior derecha del abdomen, consideramos que la torsión y la tensión del intestino delgado podrían ser más pronunciadas tras una anastomosis ileoanal. Por lo tanto, planteamos la hipótesis de que la creación de un estoma en la parte inferior izquierda del abdomen durante la anastomosis ileoanal podría reducir la incidencia de obstrucción de la salida del estoma.

***OBJETIVO:*** Evaluar si, en comparación con la colocación en el lado derecho, la colocación del estoma en el lado izquierdo reduce la incidencia de obstrucción de la salida del estoma.

***DISEÑO:*** Ensayo controlado aleatorio, abierto y unicéntrico.

***ENTORNO:*** Realizado en la Universidad Médica de Hyogo, Japón.

***PACIENTES:*** Se incluyó a un total de 181 pacientes con colitis ulcerosa que se sometieron a una anastomosis ileoanal con ileostomía entre 2018 y 2024.

***INTERVENCIONES:*** Los pacientes fueron aleatorizados para recibir una ileostomía en el lado izquierdo (grupo L, n = 91) o en el lado derecho (grupo R, n = 90).

***PRINCIPALES MEDIDAS DE RESULTADO:*** Resultado principal: incidencia de obstrucción de la salida del estoma. Resultados secundarios: duración de la estancia hospitalaria y tasa de reintervención. El análisis principal se realizó sobre la base de la intención de tratar.

***RESULTADOS:*** La incidencia de obstrucción de la salida del estoma fue significativamente menor en el grupo L (9,8 %) que en el grupo R (31,1 %; $p = 0{,}0004$). Un estoma en el lado izquierdo fue un factor protector independiente contra la obstrucción de la salida del estoma (odds ratio 0,24, intervalo de confianza del 95 % 0,10-0,56; $p = 0{,}001$). La obstrucción de la salida del estoma se asoció con una estancia hospitalaria más prolongada (mediana: 33 frente a 22 días, $p < 0{,}001$). No se encontraron diferencias significativas en las tasas de reintervención entre los grupos L y R.

***LIMITACIONES:*** Estudio de un solo centro; la generalización a otras poblaciones es incierta.

***CONCLUSIONES:*** La colocación del estoma en el lado izquierdo reduce significativamente la incidencia de obstrucción de la salida del estoma en la anastomosis ileoanal para la colitis ulcerosa y puede ser un enfoque preferible para mejorar los resultados posoperatorios. *(AI-generated translation)*

***KEY WORDS:*** Randomized controlled trial; Stoma outlet obstruction; Surgical treatment; Ulcerative colitis.

Ulcerative colitis (UC) is a chronic IBD that is characterized by diffuse colonic mucosal inflammation. Its primary symptoms include abdominal pain and bloody stools, which significantly impair patients' quality of life. First-line UC treatment is medication. In recent years, the introduction of novel therapeutic agents, including biologics, has significantly expanded the options for medical treatment. However, many patients still require surgical intervention because of refractory disease, cancer/dysplasia, or severe/fulminant conditions.

The standard surgical procedure for UC is total proctocolectomy (TPC) with IPAA, and its safety has been well documented.[1,2] During IPAA, the anastomotic site of the pouch is often at high risk of anastomotic leakage due to factors such as tension, poor nutritional status, and steroid use. Consequently, covering the ileostomy is frequently performed. Typically, the stoma is created in the right lower abdomen, following the conventional approach used in rectal surgery to cover the stoma. Indeed, large-scale clinical trials have reported that a diverting ileostomy is successfully created in 90% of cases.[2]

A significant concern in this context is stoma outlet obstruction (SOO), a form of intestinal obstruction that occurs at the stoma site. The incidence of SOO after TPC with IPAA has been reported to range from 20% to 40%.[3–6] Recent reports indicate that the SOO risk is high for 2-stage IPAA.[7] Furthermore, SOO delays the resumption of oral intake and prolongs the hospital stay.[8]

In contrast, when a stoma is created in the right lower abdomen during colorectal cancer surgery, the incidence of SOO is approximately 10%, which is notably lower than that after IPAA.[3,9–11] This difference is considered to be mainly attributable to anatomical rather than patient-related factors. Previous studies have demonstrated that the severity of UC and low serum albumin are not independent risk factors for SOO.[12] Therefore, the higher incidence of SOO after IPAA is likely related to anatomical characteristics such as the orientation, tension, and twisting of the mesentery. We hypothesized that a right-sided stoma may increase the risk of SOO due to traction on the mesentery, leading to kinking of the ileum and twisting of the mesentery. On this basis, we propose that constructing a stoma on the left side after TPC could avoid bowel torsion and allow for a more natural stoma configuration (Fig. 1). To test this hypothesis, we designed a randomized controlled trial (RCT) to compare outcomes between patients with stomas created on the traditional right side and those with stomas created on the left side.

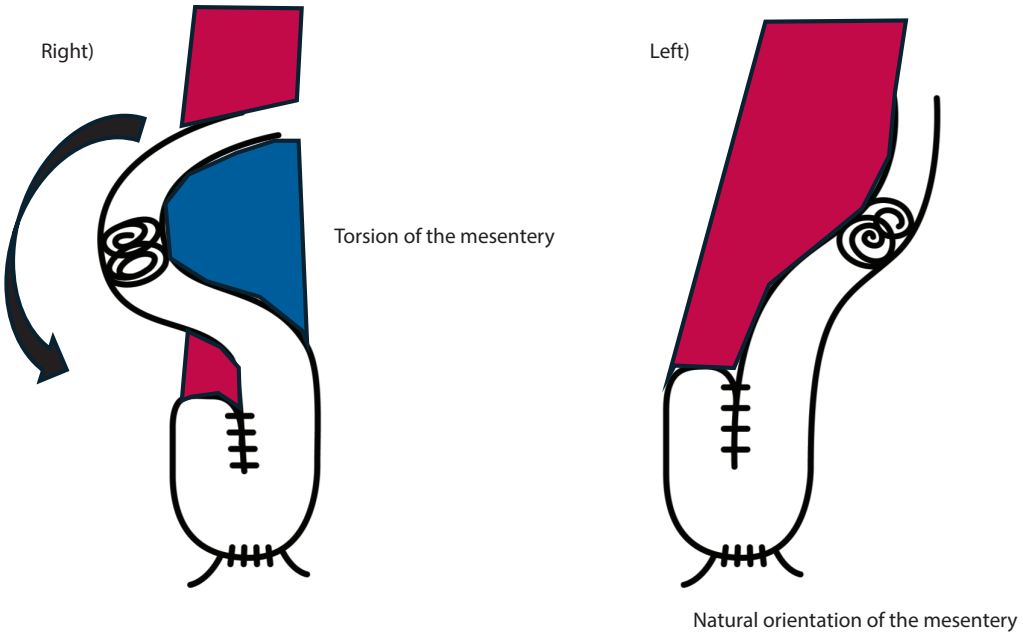


**FIGURE 1.** Right-sided and left-sided stomas associated with conventional IPAA.

## MATERIALS AND METHODS

### Study Design

This was a single-center, open-label, randomized clinical trial. We hypothesized that, in patients with UC undergoing IPAA with ileostomy, the incidence of SOO would be reduced by placing the stoma in the lower left abdomen instead of the conventional lower right abdomen. The incidence of SOO after TPC with IPAA has been reported to range from 20% to 40%.[3–6] Therefore, we hypothesized that the incidence of SOO in patients with left-sided stoma could be reduced by half. With 80% power, we estimated that 82 patients per group would be required to detect a difference in SOO rates of 20% to 40% (favoring left-sided stoma), with a type I error probability of <0.05. Considering the potential loss of evaluable patients, the total sample size was set to approximately 180.

### Ethical Considerations

All study protocols were approved by the Institutional Review Board of Hyogo Medical University (No. 2175). The study protocols were registered with the University Hospital Medical Information Network Clinical Trials Registry (UMIN-CTR 000023750). The article was prepared in accordance with the Consolidated Standards of Reporting Trials Statement (http://www.consort-statement.org).

### Patients and Group Assignment

Between January 2018 and June 2024, 392 patients underwent surgery for UC at Hyogo University Hospital. Among them, 181 patients who underwent restorative proctocolectomy, IPAA (handsewn or stapled), and ileostomy were included in this study. The study excluded patients whose informed consent could not be obtained preoperatively due to an emergency or 3-stage IPAA. Written informed consent was obtained from all participants before randomization. Treatment allocation was determined using a computerized list of block allocations. The random allocation sequence was generated by an independent coordinator. The allocation order was predetermined according to the randomization list. The included patients were assigned to either Group R or L. In Group R, the surgeon placed the stoma in the right lower abdomen following the conventional approach, whereas in Group L, the stoma was placed in the left lower abdomen.

### Perioperative Preparation

All patients received intravenous antimicrobial prophylaxis with second-generation cephalosporins 30 minutes before surgery, every 3 hours during surgery, and at 8 and 16 hours after surgery. Oral antibiotics were administered the day before surgery in patients undergoing elective surgery (3000 mg kanamycin and 3000 mg metronidazole), and mechanical bowel preparation was

performed with 1.8 L of magnesium citrate solution or 20 mL of 0.75% sodium picosulfate with hydrated magnesium citrate.

### Surgical Procedure

All patients in this study underwent total colorectal resection with either handsewn or stapled IPAA. Patients who underwent 2-stage IPAA were also included in this study. Surgery was performed with either open or laparoscopic assistance. For the handsewn anastomosis, mucosectomy and ileal pouch creation were performed by separate teams.

In some cases, subtotal colorectal resection is initially performed as an emergency procedure for acute exacerbation, followed by residual rectal resection and IPAA as secondary procedures. These patients typically had a stoma in the right lower abdomen and were excluded from this study. All surgeries were performed by a GI surgeon specializing in IBD. Laparoscopic GI procedures are always performed by a certified GI surgeon.

In most cases, a 15-cm ileal J-pouch was created without incising the ileocecal artery. A 3-row stapler was used for intestinal transection and pouch creation. A diverted ileostomy was created 50 to 60 cm proximal to the IPAA anastomotic site. The stoma was guided out of the abdominal cavity in a natural orientation without rotation. Stoma site marking was performed preoperatively on the right or left lower abdomen by a certified nurse in all cases. A longitudinal fasciotomy was performed across the rectal fascia, creating an opening large enough to accommodate both fingers.

### Outcome Measurement

The primary end point of this study was the incidence of SOO on the basis of intention-to-treat (ITT) analysis. The secondary end points were postoperative length of stay and reoperation rate. Patients who underwent reoperation during the same hospitalization and those who experienced perioperative mortality were excluded from the per-protocol (PP) analysis. SOO was defined as a small-bowel obstruction presenting with obstructive symptoms (abdominal distention and/or vomiting) and radiological evidence of caliber change and proximal bowel dilation at the stoma site on CT or contrast study. In cases where a transstomal decompression tube was inserted, resolution of dilation and resumption of gas/stool passage after decompression were considered supportive findings confirming the diagnosis. All cases of SOO were initially managed conservatively with decompression using a transstomal or transnasal ileus tube. Intestinal obstruction originating from other sites was considered to be ileus, not SOO. A gastroenterological surgeon and radiologist made the final diagnosis of SOO. Postoperative complications were classified according to the Clavien-Dindo classification.[13]

Patient characteristics included sex, age, age at UC onset, age at surgery, disease duration, BMI, height, body weight, extent of colitis, UC severity, surgical indication, ASA physical status (ASA-PS), Onodera's prognostic nutritional index (PNI), and smoking status. Preoperative blood examinations included serum albumin (Alb) and lymphocyte counts, which were both evaluated immediately before surgery. The PNI used to predict postoperative complications and mortality in patients with UC was calculated as $10 \times$ serum Alb level (g/dL) $+ 0.005 \times$ peripheral blood lymphocyte count (/mm$^3$).[14] The thickness of the abdominal wall was measured using CT imaging as previously reported.[12] Preoperative administration of corticosteroids, immunosuppressants, or tumor necrosis factor-alpha (TNF) inhibitors was defined as their administration within 12 weeks before surgery.

### Statistical Analysis

All the statistical analyses were performed using JMP version 16 (SAS Institute Inc., Cary, NC). Categorical variables were analyzed using Pearson's $\chi^2$ test or Fisher exact probability test, as appropriate, whereas continuous variables were compared with Student $t$ test for normally distributed data and the Mann-Whitney $U$ test for non-normally distributed data. To identify the independent predictors of SOO, multivariate logistic regression analysis was conducted using the forward stepwise selection method. Clinically relevant variables ($p < 0.1$ in the univariate analysis) were included in the multivariate model to adjust for potential confounders. Statistical significance was defined as a $p$ value of $<0.05$.

## RESULTS

### Study Flow

From January 2018 to June 2024, 392 patients underwent surgery for UC at Hyogo Medical University Hospital. Among them, 212 patients were scheduled to undergo IPAA. After excluding 31 patients who did not provide informed consent, 181 patients were enrolled and randomly assigned to either the right-sided stoma group (Group R, n = 90) or the left-sided stoma group (Group L, n = 91). All were included in the ITT analysis. Six patients (2 in Group R, 4 in Group L) underwent reoperation and were excluded from the PP analysis, resulting in 175 patients (88 in Group R, 87 in Group L) for analysis (Fig. 2). The primary analyses were performed in the ITT population, and the PP analyses were conducted as a subanalysis.

### Patient Backgrounds and Characteristics

As summarized in Table 1, baseline characteristics were well balanced between the Groups. The median age at surgery was 44 years in Group R and 47 years in Group L, and the median disease duration was approximately 6 and 8.5

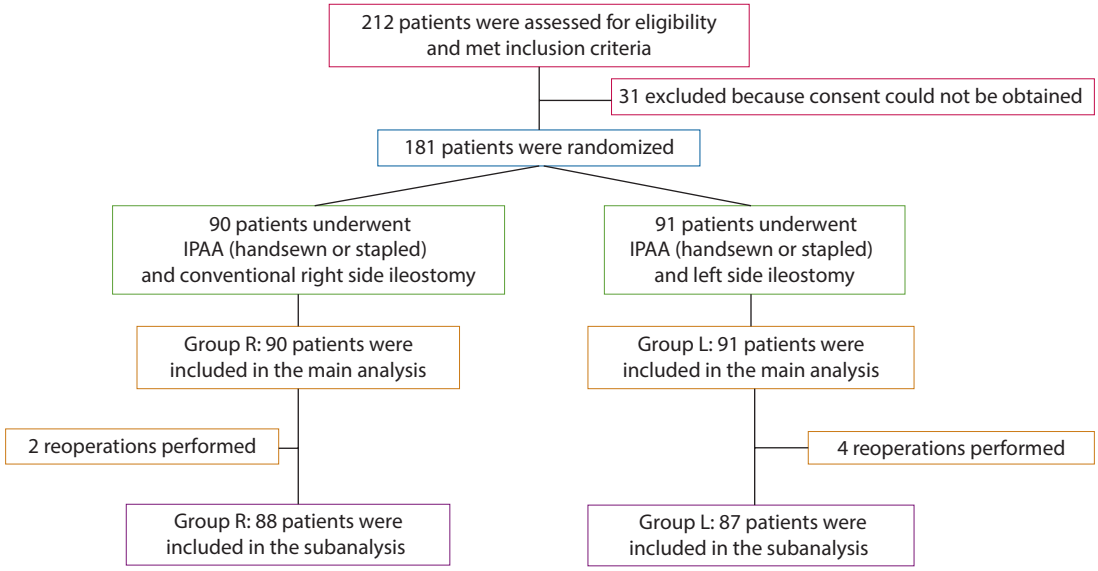


**FIGURE 2.** Flow chart of this study.

years, with no statistically significant differences between groups. The sex distribution, BMI, height, weight, and extent and severity of disease were similar. The prevalence of pancolitis was slightly higher in Group R, but this was not significant ($p$ = 0.100). Surgical indications, such as cancer/dysplasia, refractory colitis, and fulminant disease, were also comparable.

Nutritional and laboratory parameters, including ASA-PS scores, Onodera's PNI, and preoperative Alb levels, showed no significant intergroup differences. Radiological measurements, such as abdominal wall thickness, subcutaneous fat, and rectus abdominis muscle thickness, were also comparable. Preoperative treatments, including high-dose steroids (≥10,000 mg), general steroids, immunomodulators, leukocyte apheresis, and anti-TNF agents, were similarly distributed between groups. The PP analysis (see Supplemental Table 1 at https://links.lww.com/DCR/C582) confirmed no significant differences in baseline characteristics or preoperative treatments.

### *Surgical Outcomes*

Surgical outcomes are detailed in Table 2. The median operative time was 319.5 minutes in Group R and 330 minutes in Group L ($p$ = 0.355), and the volume of intraoperative blood loss was not significantly different between Groups. However, in the PP analysis (see Supplemental Table 2 at https://links.lww.com/DCR/C582), intraoperative blood loss was significantly lower in Group L ($p$ = 0.016). Most procedures were performed laparoscopically (87.7% in Group R and 93.4% in Group L, $p$ = 0.218), and handsewn IPAA was the predominant anastomotic technique in both groups. There were no significant differences in transfusion rates, postoperative complications of Clavien-Dindo grade III or higher (14.4% vs 11.0%, $p$ = 0.511), or 30-day reoperation rates (2.2% in Group R vs 4.4% in Group L, $p$ = 0.682). The causes of reoperation included small-bowel or duodenal perforation, intra-abdominal bleeding, and stoma entrapment. One patient in Group L died within 30 days postoperatively due to massive GI bleeding caused by UC-associated gastroduodenitis ($p$ = 0.608).

### *Stoma Outlet Obstruction*

A significant difference was observed in the incidence of SOO between the 2 groups. Group R had a significantly higher rate of SOO (31.1%) than did Group L (9.8%; $p$ = 0.0004), indicating a potential risk factor associated with Group R. Similarly, in the PP analysis, the incidence of SOO was significantly lower in Group L (8 patients; 9.2%) than in Group R (27 patients; 30.7%; $p$ = 0.0004). In this study, the absolute risk reduction was 21.3% (0.213) and the number needed to treat was approximately 4.7. Although the number of patients with BMI ≥25 was small (n = 22), an additional univariate analysis within the ITT population showed a lower incidence of SOO with left-sided stomas (0%) compared to right-sided stomas (37.5%; $p$ = 0.04).

All cases of SOO were managed conservatively with decompression using a transstomal or transnasal ileus tube, and no patient required endoscopic dilation, stoma revision, or reoperation for SOO within 30 days after surgery. The median time to onset of SOO was 6 days (interquartile range, 4–8) after surgery in the right-sided group and 6 days (interquartile range, 5–8) in the left-sided group, with no significant difference between the Groups ($p$ = 0.72). Six patients (2 in Group R and 4 in Group L) required reoperation within 30 days after surgery; however, none of these procedures were performed for SOO. The reasons for reoperation were intra-abdominal bleeding in 2 patients,

**TABLE 1.** Comparison of clinical characteristics between Group R and Group L

| *Variable* | *Group R (N = 90)* | *Group L (N = 91)* | *p* |
|---|---|---|---|
| Sex | | | 0.753 |
| Male | 61 (67.7%) | 59 (64.8%) | |
| Female | 29 (33.3%) | 32 (35.2%) | |
| Age at UC onset, y | 32 (5–64) | 35 (13–65) | 0.389 |
| Age at surgery, y | 44 (18–73) | 47 (18–70) | 0.4 |
| Disease duration, mo | 79.4 (0.9–590.4) | 102.4 (0.4–394.2) | 0.397 |
| BMI | 19.8 (11.0–33.8) | 20.9 (11.7–34.0) | 0.14 |
| Height, m | 1.65 (1.45–1.82) | 1.64 (1.46–1.90) | 0.76 |
| Body weight, kg | 52.5 (20.3–84.6) | 57.0 (31.5–86.2) | 0.24 |
| Extent of colitis | | | 0.1 |
| Pancolitis | 81 (90.0%) | 73 (80.2%) | |
| Left-sided colitis/other | 9 (10.0%) | 18 (19.8%) | |
| Severity | | | 0.599 |
| Mild | 44 (48.8%) | 40 (43.9%) | |
| Moderate | 27 (30.0%) | 26 (28.5%) | |
| Severe/fulminant | 19 (21.2%) | 15 (16.4%) | |
| Surgical indication | | | 0.135 |
| Cancer/dysplasia | 34 (37.8%) | 41 (45.0%) | |
| Refractory | 39 (43.3%) | 42 (46.2%) | |
| Severe/fulminant | 17 (18.9%) | 8 (8.8%) | |
| ASA-PS classification | | | 0.662 |
| 1 | 11 (12.2%) | 12 (13.1%) | |
| 2 | 69 (76.6%) | 65 (71.4%) | |
| 3 | 10 (11.1%) | 14 (15.5%) | |
| Nutritional status, Onodera's PNI | 43.2 (14.2–59.1) | 45.5 (17.9–59.2) | 0.514 |
| Preoperative albumin, mg/dL | 3.8 (1.2–4.9) | 3.8 (1.3–5.3) | 0.923 |
| Abdominal wall thickness, mm | 25.8 (7.8–60.0) | 25.9 (9.9–57.2) | 0.556 |
| Thick subcutaneous fat, mm | 15.8 (1.5–49.3) | 15.7 (1.8–45.8) | 0.39 |
| Thickness of rectus abdominis muscle, mm | 10.0 (4.2–20.1) | 9.7 (3.5–16.4) | 0.86 |
| Preoperative medication | | | |
| Total steroid dose ≥10,000 mg | 14 (15.5) | 15 (16.4) | 0.864 |
| Preoperative steroid use | 19 (21.1) | 20 (21.9) | 0.887 |
| Immunomodulator use | 55 (61.1) | 65 (71.4) | 0.159 |
| Leukocyte apheresis | 26 (28.9) | 23 (25.3) | 0.618 |
| Anti-TNF use | 38 (42.2) | 44 (48.3) | 0.456 |

Data are presented as n (%) or median (range). Group R underwent right side ileostomy; Group L underwent left side ileostomy.
ASA-PS = ASA-physical status; PNI = prognostic nutritional index; TNF = tumor necrosis factor; UC = ulcerative colitis.

**TABLE 2.** Comparison of surgery-related and postoperative factors in Group R and Group L

| *Variable* | *Group R (N = 90)* | *Group L (N = 91)* | *p* |
|---|---|---|---|
| Surgery-related factors | | | |
| Operation time, min | 319.5 (182–569) | 330 (169–674) | 0.355 |
| Blood loss, mL | 120 (10–960) | 83 (5–2140) | 0.149 |
| Transfusion | 6 (6.67) | 12 (13.2) | 0.141 |
| Surgical approach | | | 0.218 |
| Open | 11 (13.2%) | 6 (6.6%) | |
| Laparoscopy | 79 (87.7%) | 85 (93.4%) | |
| Anastomosis (IPAA) | | | 0.7 |
| Handsewn | 75 (83.3%) | 73 (80.2%) | |
| Stapled | 15 (16.7%) | 18 (19.8%) | |
| Postoperative complications (Clavien-Dindo grade ≥III) | 13 (14.4%) | 10 (11.0%) | 0.511 |
| Reoperation within 30 d after surgery | 2 (2.2%) | 4 (4.4%) | 0.682 |
| Perioperative deaths within 30 d after surgery | 0 | 1 (1.1%) | 0.608 |
| Stoma outlet obstruction | 28 (31.1) | 9 (9.8) | 0.0004 |

Group R underwent right side ileostomy; Group L underwent left side ileostomy.

small-bowel perforation in 2, duodenal perforation in 1, and stoma retraction in 1. One of these cases involved a small-bowel perforation that occurred during the insertion of a balloon catheter through the stoma, which was performed because SOO was clinically suspected.

### *Univariate Analysis of Factors Related to SOO*

Table 3 compares patients with and without SOO (n = 37 and n = 144, respectively). Patients with SOO had significantly lower BMI (median 18.8 vs 20.7, $p = 0.016$), and a shorter operative time (309 vs 331.5 minutes, $p = 0.019$). The distribution of sex, age, disease duration, and UC severity was not significantly different between groups. Nutritional status, as assessed by PNI and Alb levels, the ASA-PS score, and imaging-based measures, such as abdominal wall thickness, were all similar.

Preoperative treatments did not differ significantly between the SOO and non-SOO groups, including use of steroids, immunomodulators, apheresis, and anti-TNF agents. Notably, the frequency of left-sided stoma was significantly lower in the SOO group (24.2% vs 56.9%, $p < 0.001$), and the postoperative hospital stay was significantly longer (median 33 vs 22 days, $p < 0.001$). The PP analysis (see Supplemental Table 3 at https://links.lww.com/DCR/C582) confirmed that SOO was associated with lower BMI, shorter operation time, fewer left-sided stomas, and longer hospital stay. Other variables remained nonsignificant.

**TABLE 3.** Univariate analysis of risk factors associated with SOO

| *Variable* | *SOO group (N = 37)* | *Non-SOO group (N = 144)* | *p* |
|---|---|---|---|
| Sex | | | 0.117 |
| Male | 29 (78.3%) | 91 (63.2%) | |
| Female | 8 (21.7%) | 52 (36.8%) | |
| Age at UC onset, y | 33 (12–60) | 34 (7–65) | 0.794 |
| Age at surgery, y | 44 (18–67) | 47 (18–73) | 0.149 |
| Disease duration, mo | 72.2 (0.9–427.8) | 102.3 (0.4–590.4) | 0.355 |
| BMI | 18.8 (12.6–29.1) | 20.7 (11.7–34.0) | 0.016 |
| Height, m | 1.66 (1.45–1.90) | 1.64 (1.40–1.81) | 0.609 |
| Body weight, kg | 49.0 (30.4–79.2) | 57.0 (31.5–86.2) | 0.113 |
| Extent of colitis | | | 0.605 |
| Pancolitis | 33 (89.1%) | 121 (84.0%) | |
| Left-sided colitis/other | 4 (10.9%) | 23 (16.0%) | |
| Severity | | | 0.908 |
| Mild | 18 (48.6%) | 66 (45.8%) | |
| Moderate | 11 (29.7%) | 42 (29.2%) | |
| Severe/fulminant | 8 (21.7%) | 36 (25.0%) | |
| Surgical indication | | | 0.404 |
| Cancer/dysplasia | 12 (32.4%) | 63 (43.8%) | |
| Refractory | 20 (54.1%) | 61 (42.3%) | |
| Severe/fulminant | 5 (13.5%) | 20 (13.9%) | |
| ASA-PS classification | | | 0.584 |
| 1 | 5 | 18 | |
| 2 | 29 | 105 | |
| 3 | 3 | 21 | |
| Nutritional status, Onodera's PNI | 44.5 (23.9–59.2) | 44.7 (14.2–58.1) | 0.549 |
| Preoperative albumin, mg/dL | 3.8 (2.2–4.9) | 3.9 (1.2–5.3) | 0.808 |
| Abdominal wall thickness, mm | 25.8 (7.8–60.0) | 25.9 (9.9–57.2) | 0.556 |
| Thick subcutaneous fat, mm | 12.9 (1.8–36.0) | 16.7 (1.5–49.3) | 0.065 |
| Thickness of rectus abdominis muscle, mm | 9.85 (3.5–15.3) | 9.7 (4.2–20.1) | 0.868 |
| Preoperative medication | | | |
| Total steroid dose ≥10,000 mg | 5 (13.5) | 24 (16.7) | 0.803 |
| Preoperative steroid use | 6 (16.2) | 33 (22.9) | 0.502 |
| Immunomodulator use | 29 (78.3) | 91 (63.2) | 0.118 |
| Leukocyte apheresis | 10 (27.0) | 39 (27.1) | 1 |
| Anti-TNF use | 18 (48.6) | 64 (44.4) | 0.712 |
| Surgical outcome | | | |
| Open/laparoscopic | 3/34 | 14/130 | 1 |
| Operation time, min | 309 (182–416) | 331.5 (169–674) | 0.019 |
| Blood loss, mL | 100 (10–670) | 100 (5–2140) | 0.92 |
| Transfusion | 1 (2.7) | 17 (11.8) | 0.128 |
| Left-sided stoma | 9 (24.2) | 82 (56.9) | <0.001 |
| Postoperative hospital stay, d | 33 (13–65) | 22 (10–55) | <0.001 |

Data are presented as n (%) or median (range).
ASA-PS = ASA Physical Status; PNI = prognostic nutritional index; SOO = stoma outlet obstruction; TNF = tumor necrosis factor; UC = ulcerative colitis.

### *Multivariate Analysis of Factors Related to SOO*

In the multivariate model (Table 4), the only independent factor significantly associated with a reduced risk of SOO was the presence of a left-sided stoma (OR 0.26; 95% CI, 0.11–0.61; $p = 0.001$). Although BMI <17.2 (OR 2.74, $p = 0.072$) and operative time >324 minutes (OR 0.51, $p = 0.131$) were significant in univariate analysis, they did not retain statistical significance in the multivariate model. These findings were supported by the PP analysis (see Supplemental Table 4 at https://links.lww.com/DCR/C582), which also identified left-sided stoma as the sole independent protective factor for SOO.

## *DISCUSSION*

This study is the first RCT to show that a left-sided stoma, conventionally placed on the right, significantly reduces the incidence of SOO during 2-stage IPAA for UC. This RCT was inspired by the low SOO incidence of approximately 10% when a similar covering stoma is created for a low anterior resection. In general colorectal surgery, such as low anterior resection, the construction of a diverting ileostomy in the right lower quadrant is anatomically natural because the terminal ileum runs toward the cecum, which is preserved. However, in IPAA, the colon is resected and the ileal pouch is reconstructed deep within the pelvis. Creating a right-sided stoma in this setting requires the small bowel to cross the midline and take a longer, more tortuous route, resulting in an unnatural bowel orientation. This configuration may increase mesenteric torsion and tension, contributing to the development of SOO.

In contrast, a left-sided stoma provides a smoother and more physiological alignment of the mesentery between the stoma and the ileal pouch. We speculate that creating a stoma in the left lower abdomen might allow a more natural flow of the mesentery to the ileal pouch, thereby preventing SOO. The results of this study revealed that left-sided stoma had a significantly lower incidence of SOO (9/91 [9.8%]) than did conventional right-sided stoma (28/90 [31.1%]; $p = 0.0004$). Multivariate analysis revealed that a left stoma was an independent factor associated with a reduced risk of SOO (OR 0.24; 95% CI, 0.10–0.56).

SOO is a common postoperative complication of IPAA in patients with UC. The incidence rate of SOO has been reported to be 20% to 40%.[3–6] The incidence of SOO in patients with right-sided stoma was as high as 31.1% (28/90) in this study. SOO is of high clinical importance because it prolongs hospital stays and increases health care costs. In this study, the SOO group had a significantly longer postoperative hospital stay (33 [13–65] days vs 22 [10–55] days; $p \leq 0.001$). Various risk factors have been reported, including bowel torsion and tension, thickness of the rectus abdominis muscle or subcutaneous fat, and laparoscopic surgery.[4,15–17] Many of the reported risk factors for SOO may predict SOO, but preventing SOO is difficult. Stoma construction on the left side may prevent SOO by simply changing the position of the stoma.

Outlet obstruction is rarely observed in the early postoperative period, particularly within the first week after surgery. Most cases occur between 1 and 2 weeks postoperatively, coinciding with sufficient oral intake. Factors contributing to this delay may include increased bowel motility, increased stool viscosity, and mucosal edema. The intraluminal pressure in the small intestine is generally lower than that in the large intestine. As a result, even minor adhesions can obstruct passage through the small intestine. This characteristic highlights the vulnerability of the small intestine to outlet obstruction under specific postoperative conditions.[9] When SOO occurs, a decompression tube may be inserted from the stoma to the ileum, which is easily decompressed by inserting it beyond the site of the obstruction causing the SOO. In addition, a small-bowel angiogram may be performed to identify the site of obstruction. However, intestinal perforation may occur during tube insertion. This was observed in 1 case in the present study. Refractory SOO also increases the rate of reoperations, including stoma reconstruction. It is suggested that SOO can be prevented by changing the position of the stoma, thereby avoiding complications associated with tube insertion and reoperation. From this perspective, this approach would be beneficial.

Minimally invasive surgery for UC has been progressing, and laparoscopic surgery has been performed for UC since 2000. According to previous reports, laparoscopic surgery is a risk factor for SOO in patients with UC. The incidence of SOO for laparoscopic surgery is 29%, whereas

**TABLE 4.** Multivariate analysis of risk factors associated with SOO

| | | | *Multivariate analysis* | |
|---|---|---|---|---|
| *Variable* | *SOO group (N = 37)* | *Non-SOO group (N = 144)* | *p* | *OR (95% CI)* |
| BMI | 18.8 (12.6–29.1) | 20.7 (11.7–34.0) | 0.342 | 0.92 (0.78–1.08) |
| Thick subcutaneous fat, mm | 12.9 (1.8–36.0) | 16.7 (1.5–49.3) | 0.826 | 0.99 (0.92–1.06) |
| Operation time, min | 309 (182–416) | 331.5 (169–674) | 0.394 | 1.00 (0.98–1.00) |
| Left-sided stoma | 9 (24.2) | 82 (56.9) | 0.001 | 0.26 (0.11–0.61) |

Data are presented as n (%) or median (range).
SOO = stoma outlet obstruction.

for open surgery it is 19.6%, which is significantly lower.[15] In this study, 90.6% of the procedures (164/181) were performed laparoscopically. The incidence of SOO in patients with a right stoma was 31.6% (25/79), as previously reported. The incidence of SOO in left stoma patients was 10.5% (9/85), which was significantly lower ($p$ = 0.001). The use of a left stoma may be useful in preventing SOO in patients undergoing laparoscopic surgery. Although we hypothesized that a right-sided stoma may contribute to SOO by inducing mesenteric traction or torsion, this mechanism could not be clearly demonstrated in the present study. In fact, in typical right-sided stoma construction, the oral limb naturally runs to the left of the stoma. However, in patients who developed SOO, as illustrated in Figures 3 and 4, the oral limb was located to the right of the stoma, suggesting an unnatural bowel configuration. In addition, CT images often showed narrowing at the fascial level, which may contribute to outlet obstruction. In contrast, definitive radiologic evidence of mesenteric torsion or traction was not identified, as such dynamic factors are inherently difficult to evaluate objectively with current imaging modalities. These findings suggest that the cause of SOO likely involves a combination of anatomical and technical factors, such as fascial constriction and narrowing of the subcutaneous tunnel. Thus, our hypothesis should be interpreted as part of a broader concept of mechanical stress at the stoma site, rather than a single causative mechanism.

Notably, although low BMI has been reported as a risk factor for SOO, it was not found to be an independent predictor in this study. Other factors analyzed included abdominal wall thickness and rectus abdominis muscle thickness, which were not independent risk factors for SOO. Previous studies have reported that patients with higher BMI and thicker subcutaneous fat have an increased risk of SOO due to mechanical compression at the stoma site.[3,4] In contrast, our study identified low BMI as a risk factor for SOO, whereas subcutaneous fat thickness itself was not associated with SOO occurrence. This apparent discrepancy may be explained by differences in the underlying pathophysiological mechanisms. Although this subgroup analysis suggests that the protective effect of a left-sided stoma may extend to patients with higher BMI, the limited sample size precludes firm conclusions, and these findings should be interpreted with caution. In patients with low BMI, reduced mesenteric fat may increase mesenteric mobility, predisposing the bowel to twisting or kinking, which could in turn lead to SOO. Therefore, both excessive subcutaneous fat and insufficient mesenteric fat may contribute to SOO development through distinct anatomical pathways.[12] Even if these were risk factors, preoperative risk reduction would be difficult due to their nature.

This study is significant in that it demonstrates that surgical intervention may reduce the risk of SOO. One method that has been reported for surgically preventing SOO is to perform 3-stage segmentectomy or modified 2-stage surgery.[7] However, although this method may be effective for refractory cases, it may not be applicable to cancer and dysplasia cases. This is because most cancers and dysplasia associated with UC occur from the sigmoid colon to the rectum, where UC inflammation is severe. In fact, it has been reported that more than 70% of cases occur from the sigmoid colon to the anorectal side.[18] Surgery resulting in a neoplastic lesion in the residual bowel tract is not ideal. Because these patients were treated with 2-stage IPAA, the creation of a left stoma for SOO prophylaxis is recommended. Owing to

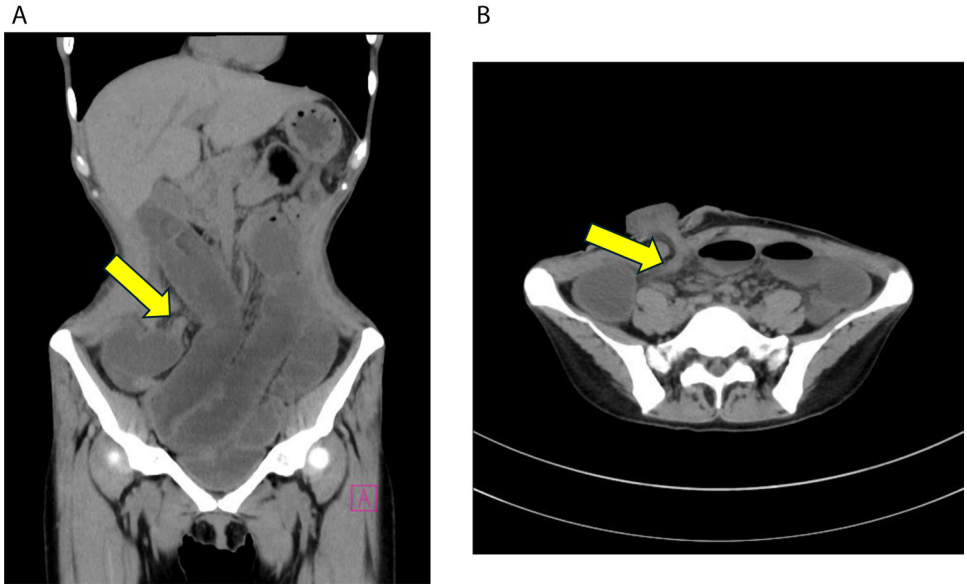


**FIGURE 3.** Abdominal CT images demonstrating stenosis at the stoma outlet. A, Abdominal CT image, coronal section: the yellow arrow indicates stenosis at the stoma outlet. B, Abdominal CT image, axial section: the yellow arrow indicates stenosis at the stoma outlet.

**FIGURE 4.** Contrast study from the stoma: the oral side small intestine is dilated.

the limited number of patients in the present study, no significant differences were observed in the occurrence of severe complications of Clavien-Dindo grade 3 or higher. However, it can be inferred that complications such as bowel perforation and stoma subsidence associated with decompression from the stoma may decrease with SOO prophylaxis.

This study has several limitations. First, it was conducted at a single center, and our hospital is a specialized facility with an IBD center, which means that many patients may have had severe IBD. Second, this study included only Japanese patients, so it is unclear whether the findings apply to Western populations. Third, because this was an open-label trial, the surgeons' decisions may have influenced the results. Fourth, the study did not include postoperative follow-up data, such as information on ileostomy closure. Finally, 2-stage reconstructive surgery after total colectomy was not covered in this study. Further multicenter studies with more diverse patient populations are warranted to validate our results.

## CONCLUSIONS

This RCT demonstrated that constructing a left-sided stoma significantly reduced the incidence of SOO during 2-stage IPAA for UC compared with the conventional right-sided approach. These findings suggest that stoma location is a modifiable surgical factor that may contribute to SOO prevention.

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