

Clinical Outcomes After Restorative Proctocolectomy With Ileal Pouch Anal Anastomosis Using Ultrasonically Activated Scalpel for Ulcerative Colitis

Hiroki Ikeuchi^{1,2}, Motoi Uchino^{1,2}, Hiroki Matsuoka^{1,2}, Toshihiro Bando^{1,2}, Yoshio Takesue³, Naohiro Tomita²

¹*Inflammatory Bowel Disease Center, Hyogo College of Medicine, Hyogo, Japan*

²*Department of Surgery, Hyogo College of Medicine, Hyogo, Japan*

³*Department of Infection Control and Prevention, Hyogo College of Medicine, Hyogo, Japan*

We compared 3 different initial operative procedures performed in patients with ulcerative colitis who underwent an ileal pouch anal anastomosis (IPAA) procedure with a Harmonic Scalpel (HS). We selected 775 patients who underwent a restorative proctocolectomy with a mucosectomy using an HS and hand-sewn IPAA. Ninety-six patients underwent a total colectomy (3-stage procedure) as the initial operation, whereas 258 underwent IPAA without ileostomy (1-stage procedure) and 421 underwent IPAA with ileostomy (2-stage procedure). There were no significant differences regarding early pouch functional rate among the 3 groups. After 5 years with a functioning ileal pouch, the survival rates for the total colectomy, IPAA with ileostomy, and IPAA without ileostomy groups were 100%, 99.3%, and 99.0%, respectively. There was low operative mortality, and acceptable rates of early and late complications in patients with ulcerative colitis who underwent a restorative proctocolectomy and IPAA using an HS.

Key words: Ulcerative colitis – Ileal pouch anal anastomosis – Mucosectomy – Ultrasonically activated scalpel

Ulcerative colitis (UC) is a disease of unknown etiology that affects all or part of the large bowel. Although the primary treatment is medical, it is estimated that the 10-year cumulative colectomy rate ranges from 20% to 30%.^{1,2} Typically, patients with UC have a strong desire to avoid receiving a permanent ileostomy, thus ileal pouch anal anastomosis (IPAA) has become the procedure of choice for these cases.

Although a mucosectomy is generally a difficult procedure for general surgeons, with recent advances in stapling techniques, many now perform IPAA without a mucosectomy using a circular stapler. Nevertheless, a mucosectomy offers several important advantages. Leaving diseased mucosa exposes the patient to increased risk of residual proctitis in the setting of UC and carcinoma development. In our department, we previously performed transanal mucosectomy procedures with a forceps coagulation technique using a monopolar electrocoagulator.³ However, use of an electrocoagulator has been suggested to be harmful to the anal sphincter.⁴ Because maintenance of quality of life is difficult with poor postoperative sphincter function, we generally attempt to establish a nonfunctioning ileostomy to divert the fecal stream until the internal sphincter has recovered and IPAA healing is confirmed.

In 1997, we began using an ultrasonically activated scalpel [Harmonic Scalpel (HS), Ethicon Endo-Surgery, Inc, Cincinnati, Ohio] to simplify and modify our technique.⁴ With an HS, we are able to perform a mucosectomy without injuring the remaining internal sphincter, compared with our previous procedure with an electrocoagulator. Introduction of this technique has enabled us to perform 1-stage IPAA procedures in selected patients with UC since November 1999.

For the present study, we compared perioperative clinical characteristics, postoperative mortality, and early and late pouch functional rates among 3 different initial operative procedures used in UC patients with IPAA performed with an HS.

Patients and Methods

Patients

From November 1999 to December 2009, 852 patients with UC underwent an operation at Hyogo College of Medicine. Their procedures were prospectively monitored and the data entered into an Excel database. For this study, we selected 775 patients who underwent a restorative proctocolectomy (RPC) with a mucosectomy performed with an HS and hand-sewn IPAA. We excluded patients whose operative procedure was restorative RPC

without a mucosectomy using a double-stapled technique, ileorectal anastomosis, or total proctocolectomy with permanent ileostomy.

Selection of initial operative procedures (number of operation stages)

The number of stages used did not follow strict guidelines, as surgical judgment was based on the severity of colitis at the time of the first operation and clinical condition of the patient. When a 3-stage operation was performed, a total colectomy, suprapubic mucous fistula, and ileostomy were used as the first operation. IPAA with ileostomy was then performed 3 months after the first operation, with an additional 3 months necessary for final stoma closure. When a 2-stage operation was performed, RPC and IPAA with ileostomy were used as the first operation, then ileostomy closure was performed 3 months after the first operation. In cases with a single-stage procedure, RPC and IPAA without ileostomy were used as the first operation. Patients were considered for an RPC without ileostomy if they had disease previously diagnosed as UC (excluding Crohn's disease), and were without an anal fistula or perianal abscess. In addition, we excluded patients with fulminant colitis, toxic megacolon, or perforation. The IPAA was also to be performed under with absolutely no tension. When these conditions did not apply, a diverting loop ileostomy was constructed proximal to the pouch. If a patient desired a 2-stage operation, we constructed an ileostomy.

Operative techniques

The surgical procedure used was a standard method that consisted of an abdominal proctocolectomy and complete transanal mucosectomy using an HS in the Lloyd-Davis position.

Total colectomy and ileal J-pouch

A lower median incision was performed in the usual manner. Two abdominal surgeons performed a total colectomy and anterior resection of the rectum using normal procedures. A 15-cm ileal J-pouch was then constructed using 4 white reload (1.0 mm closed staple height) of the Echelon 60 Endopath Staplers (Ethicon Endo-Surgery, Cincinnati, Ohio).

Mucosectomy

When an HS was used, the anal canal was first dilated carefully with an anal retractor, then 6 stay sutures were placed around the anus, which was

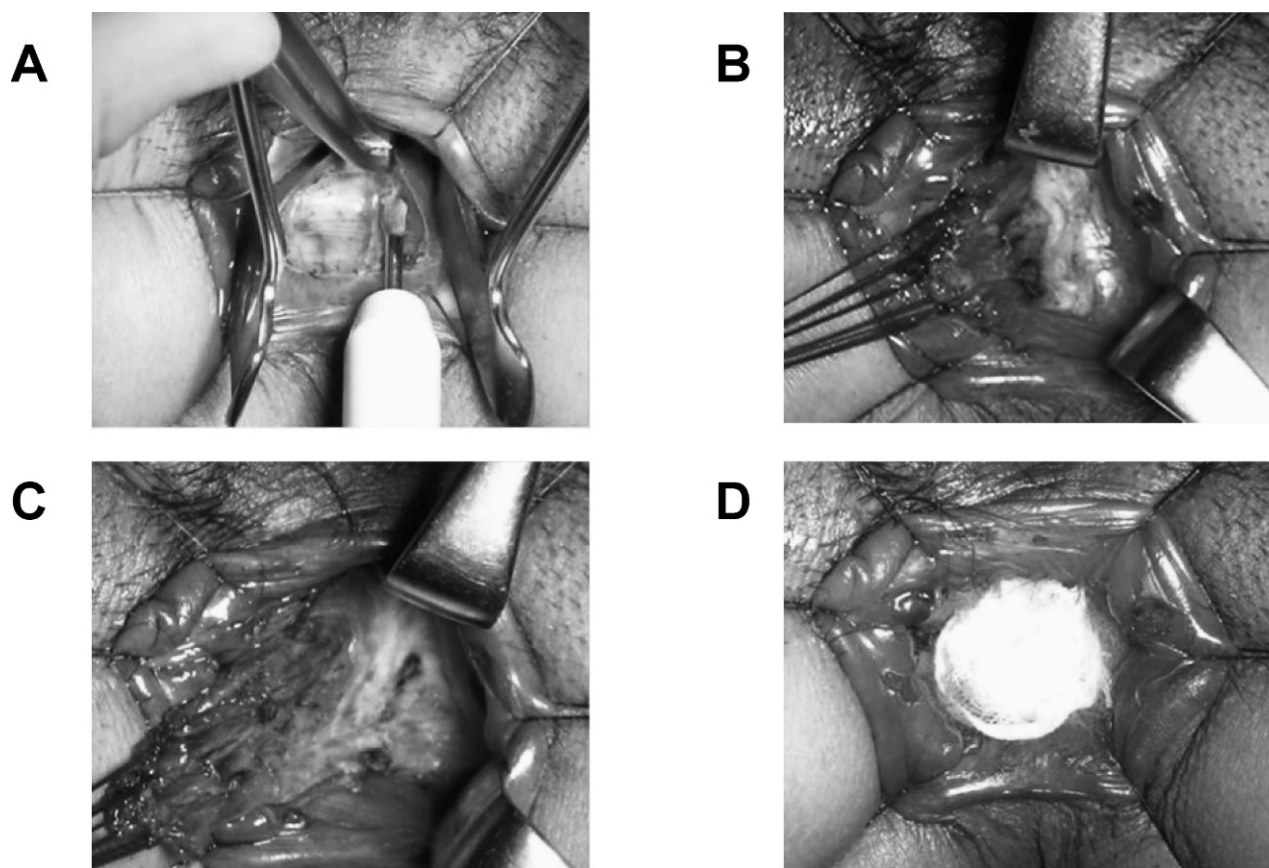


Fig. 1 Operative procedures for mucosectomy using HS. (A) Circumferential dissection of anorectal mucosa at the dentate line. (B) The distal stump was closed with several stitch sutures and the mucosectomy was continued upward with traction of these threads. (C) Completion of graduated mucosal proctectomy. (D) Pushback of distal rectum to the abdominal cavity.

stretched to expose the anal canal. Adrenaline diluted to 0.02% in a saline solution was injected into the submucosal layer to reduce bleeding and facilitate dissection of the rectal mucosa. The mucosa was then cut circumferentially at the upper margin of the dentate line with the HS (Fig. 1A). Once the dissection had been extended around the anal canal to create a mucosal tube, the distal stump was closed with several stitch sutures to prevent contamination of the internal anal sphincter. The mucosectomy was continued upward with traction of these threads (Fig. 1B). The anorectal mucosa was completely stripped 2 to 3 cm from the dentate line above the levator muscle, then graduated cutting of the rectal wall was performed (Fig. 1C). Finally, the dissected rectum was pushed upward into the abdominal cavity with gauze pads (Fig. 1D).

Ileal J-pouch anal anastomosis

We performed 4 stay sutures between the pouch and internal sphincter (Fig. 2A), then the IPAA was

hand-sewn with 24 stitches (Fig. 2B). The pouch was decompressed transanally by insertion of a 28F catheter (Fig. 2C).

Data analysis

Grouped data are expressed as the median and range. All data were compared by a χ^2 test. The cumulative probability of pouch success over time after IPAA was estimated using the Kaplan-Meier method, with survival curves compared with a log rank test. Statistical significance was set at $P < 0.05$.

Results

Choice of operation

The surgical details are summarized in Table 1. During the follow-up period, we performed a UC operation in 852 patients, of whom 775 (91%) underwent a hand-sewn IPAA. Ninety-six patients underwent a total colectomy as the initial operation,

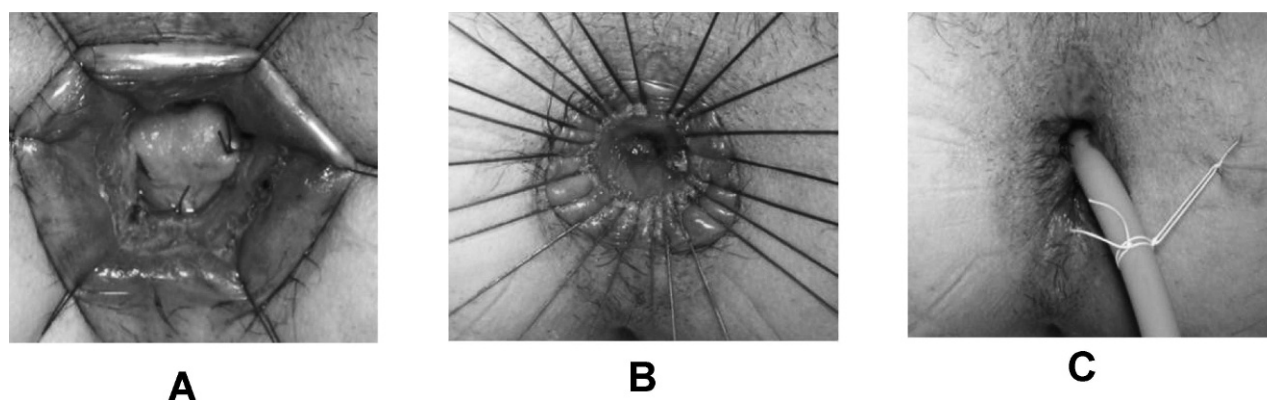


Fig. 2 Operative procedures for ileal J-pouch anal anastomosis. (A) Four stay sutures were used between the pouch and internal sphincter. (B) The IPAA was hand-sewn using 24 stitches. (C) The pouch was decompressed transanally by insertion of a 28F catheter.

whereas 258 underwent IPAA without ileostomy (1-stage procedure) and the remaining 421 patients underwent IPAA with ileostomy (2-stage procedure).

Surgical indications

The indications for surgery in patients who underwent IPAA are shown in Table 2. There were significant differences for incidence of emergency operations among the groups. Refractory medical therapy was the most common indication in all groups. Recently, the number of patients with a preoperative diagnosis of colitis-associated colorectal cancer or dysplasia has been gradually increasing. In the present study, only 3.5% patients in the IPAA without ileostomy group underwent an emergency operation and the only operative indication in those was hemorrhage. That symptom emerged rapidly 1 or 2 days before surgery, therefore the general condition of those patients was not seriously deteriorated. The decision to omit the ileostomy was based on preoperative and operative conditions. We excluded IPAA without ileostomy in patients with

acute complications of UC such as fulminant colitis, toxic megacolon, and perforation.

Patient characteristics

The clinical characteristics and preoperative treatments are shown in Tables 3 and 4, respectively. There were significant differences in median age at the initial operation between the IPAA without ileostomy group and the other 2 groups [total colectomy group, 36 years old (14–81 years) versus IPAA without ileostomy group, 32 years old (15–69 years), $P < 0.01$; IPAA with ileostomy group, 39 years old (11–69 years) versus IPAA without ileostomy group, 32 years old (15–69 years), $P < 0.01$]. The duration from onset to operation in the IPAA with and without ileostomy groups was more than that in the total colectomy group [total colectomy group, 34.0 months (0.3–338.6 months) versus IPAA with ileostomy group, 80.2 months (0.7–457.6 months), $P < 0.01$; total colectomy group, 34.0 months (0.3–338.6 months) versus IPAA without ileostomy group, 80.8 months (2.6–304.5 months),

Table 1 Initial operative plans for all patients

	Initial operation	Operative procedure	No. of patients
IPAA with mucosectomy	Total colectomy (TC)	TC → IPAA with ileostomy → SC	86
		TC → IPAA without ileostomy	10
	IPAA with ileostomy	IPAA with ileostomy → SC	421
	IPAA without ileostomy		258
Stapled IPAA			20
IRA			9
TPC			46
Miscellaneous			2
Total			852

IPAA, ileal pouch anal anastomosis; IRA, ileorectal anastomosis; SC, stoma closure; TPC, total proctocolectomy.

Table 2 Indications for surgery

Initial operation	Total colectomy (n = 96) (%)	IPAA with ileostomy (n = 421) (%)	IPAA without ileostomy (n = 258) (%)
Emergency surgery	69 (71.9)	70 (16.6) ^a	9 (3.5) ^{b,c}
Hemorrhage	20	33	9
Fulminant colitis	18	26	0
Perforation	20	2	0
Elective surgery	27 (28.1)	351 (83.4) ^a	249 (96.5) ^{b,c}
Refractory medical therapy	21	292	212
Dysplasia or cancer	2	50	21
Colonic stricture	4	9	13
Extraintestinal manifestation	0	0	3

^aSignificant difference between total colectomy and IPAA with ileostomy groups.

^bSignificant difference between IPAA with and without ileostomy groups.

^cSignificant difference between total colectomy and IPAA without ileostomy groups.

IPAA, ileal pouch anal anastomosis.

$P = 0.01$]. There was no statistically significant difference between the IPAA with and without ileostomy groups [IPAA with ileostomy group, 80.2 months (0.7–457.6 months) versus IPAA without ileostomy group, 80.8 months (2.6–304.5 months), $P = 0.09$]. The total corticosteroid dose in the total colectomy group was significantly lower than that in the other 2 groups [total colectomy group, 6750 mg (0–51,100 mg) versus IPAA with ileostomy group, 10,083 mg (0–132,875 mg), $P < 0.01$; total colectomy group, 6750 mg (0–51,100 mg) versus IPAA without ileostomy group, 11,000 mg (0–87,600 mg), $P < 0.01$; IPAA with ileostomy group, 10,083 mg (0–132,875 mg) versus IPAA without ileostomy group, 11,000 mg (0–87,600 mg), $P = 0.01$]. The daily corticosteroid dose in the total colectomy group was significantly more than that in the other 2 groups [total colectomy group, 40 mg (0–80 mg) versus IPAA with ileostomy group, 20 mg (0–80 mg), $P < 0.01$; total colectomy group, 40 mg (0–80 mg) versus IPAA without ileostomy group, 15 mg (0–60 mg), $P < 0.01$; IPAA with ileostomy group, 20 mg (0–80 mg)

versus IPAA without ileostomy group, 15 mg (0–60 mg), $P < 0.01$].

Early postoperative pouch functional rate

Total colectomy group

The outcomes in the total colectomy group are shown in Fig. 3. Six patients died after the initial operation, 3 from postoperative sepsis, 2 from pneumonia, and 1 from advanced colorectal cancer. Eight patients did not undergo a subsequent operation, whereas 4 underwent amputation of the rectum, each of whom had a perianal or perirectal abscess and fistula before the initial operation. We performed IPAA with ileostomy in 68 patients and IPAA without ileostomy in 10 patients. Ileostomy closure could not be performed in 3 of the 68 patients in the IPAA with ileostomy group due to pelvic abscess ($n = 2$) and poor sphincter function ($n = 1$). There were no postoperative pouch-related complications in the 10 patients in the IPAA without ileostomy group. Thus, the early postoperative

Table 3 Patient characteristics

Initial operation	Total colectomy (n = 96)	IPAA with ileostomy (n = 421)	IPAA without ileostomy (n = 258)
Median age at operation (years)	36 (14–81)	39 (11–69)	32 (15–69) ^{b,c}
Sex (M/F)	56/40	238/183	133/125
Duration of disease (months)	34.0 (0.3–338.6)	80.2 (0.7–457.6) ^a	80.8 (2.6–304.5) ^c

^aSignificant difference between total colectomy and IPAA with ileostomy groups.

^bSignificant difference between IPAA with and without ileostomy groups.

^cSignificant difference between total colectomy and IPAA without ileostomy groups.

IPAA, ileal pouch anal anastomosis.

Table 4 Preoperative treatments

	Total colectomy (n = 96)	IPAA with ileostomy (n = 421)	IPAA without ileostomy (n = 258)
Total steroid dose (mg)	6750 (0–51,100)	10,083 (0–132,875) ^a	11,000 (0–87,600) ^{b,c}
Daily steroid dose (mg)	40 (0–80)	20 (0–80) ^a	15 (0–60) ^{b,c}
Immunosuppressive drugs (%)	11 (12.4)	112 (26.6) ^a	45 (17.4) ^b
Leukocytapheresis (%)	44 (45.8)	255 (60.6) ^a	138 (53.5)

^aSignificant difference between total colectomy and IPAA with ileostomy groups.

^bSignificant difference between IPAA with and without ileostomy groups.

^cSignificant difference between total colectomy and IPAA without ileostomy groups.

IPAA, ileal pouch anal anastomosis.

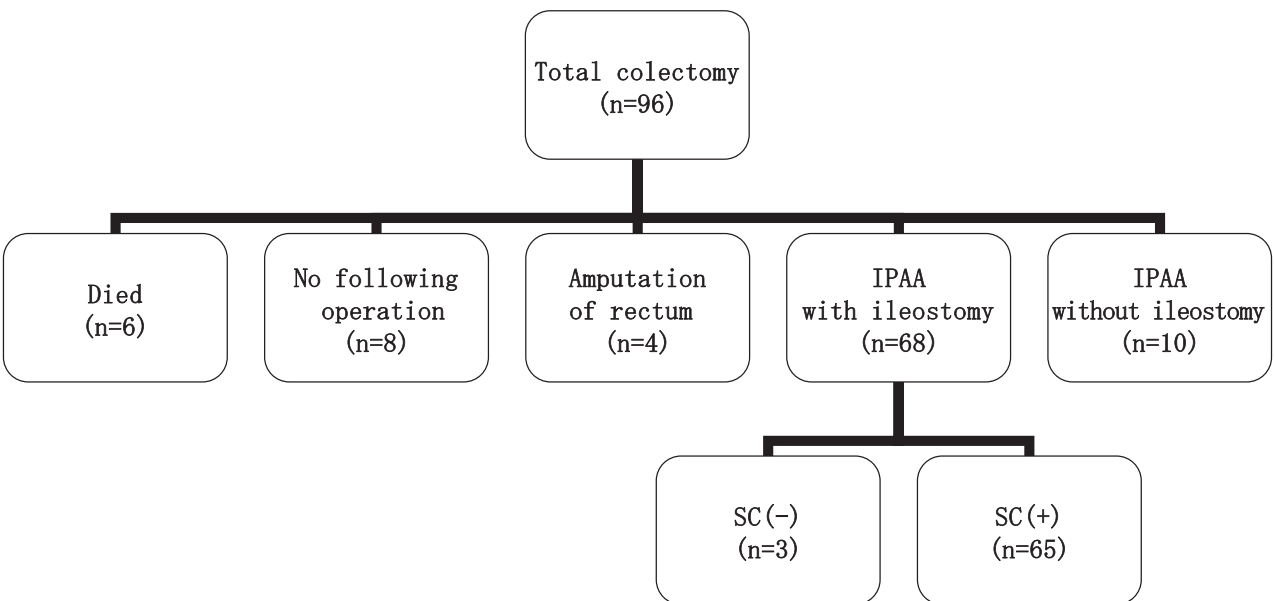
(within 1 month after the operation) pouch functional rate in the total colectomy group was 96.2%.

IPAA with ileostomy group

The outcomes in the IPAA with ileostomy group are shown in Fig. 4. Four patients died after the initial operation, 2 from postoperative pneumonia and 2 from pneumonia and postoperative sepsis. Eight patients did not undergo ileostomy closure and 3 did not undergo a subsequent ileostomy closure. Five patients had postoperative pouch-related complications, all of which were pelvic abscesses due to complications after the initial operation. Thus, the early postoperative pouch functional rate in the IPAA with ileostomy group was 98.1%.

IPAA without ileostomy group

The outcomes in the IPAA without ileostomy group are shown in Fig. 5. There were no postoperative deaths. Twelve patients underwent construction of an ileostomy after the initial operation, of whom 11 had pouch-related complications and 1 was complicated with pelvic bleeding after the operation. Eleven of those 12 patients had already received ileostomy closure and the pouch was functioning at the latest follow-up examination, whereas the other patient did not undergo ileostomy closure because of a fistula from the pouch. Thus, the early postoperative pouch functional rate in the IPAA without ileostomy group was 99.6%.



SC: Stoma closure

Fig. 3 Outcomes of patients who underwent a total colectomy as the initial operation. SC, stoma closure.

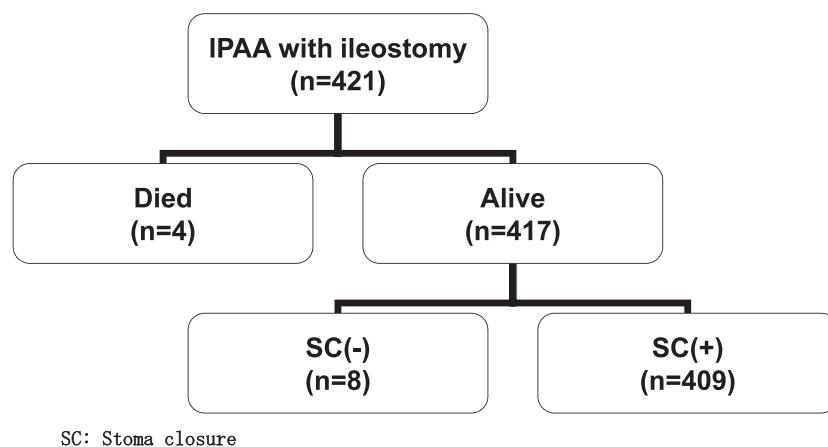


Fig. 4 Outcomes of patients who underwent IPAA with ileostomy as the initial operation. SC, stoma closure.

Outcomes of all procedures

Table 5 shows postoperative death and early postoperative pouch functional rates for all patients based on the initial operative procedure. The incidence of postoperative death in the total colectomy group was significantly more than that in the other 2 groups. There was no significant difference regarding early pouch functional rate among the 3 groups.

Long-term postoperative pouch functional rates

All patients

The cumulative pouch functional rates are shown in Fig. 6. The pouch functional rate for all patients with a functioning ileal pouch after 5 years was 99.1%.

Results after initial operation

The cumulative pouch functioning rates based on the initial operation are presented in Fig. 7 and were

not significantly different among the groups. After 5 years with a functioning ileal pouch, the rates for the total colectomy, IPAA with ileostomy, and IPAA without ileostomy groups were 100%, 99.3%, and 99.0%, respectively. Two patients in the IPAA with ileostomy group were complicated by a pelvic abscess after ileostomy closure. One patient underwent reconstruction of the ileostomy due to poor sphincter function. Two patients in the IPAA without ileostomy group were complicated with a pouch-vaginal fistula after the initial operation, of whom 1 underwent pouch excision and had a final diagnosis of Crohn's disease.

Discussion

A proctocolectomy with IPAA is generally the procedure of choice for patients with UC refractory to medical therapy and there have been numerous technical modifications designed to improve its

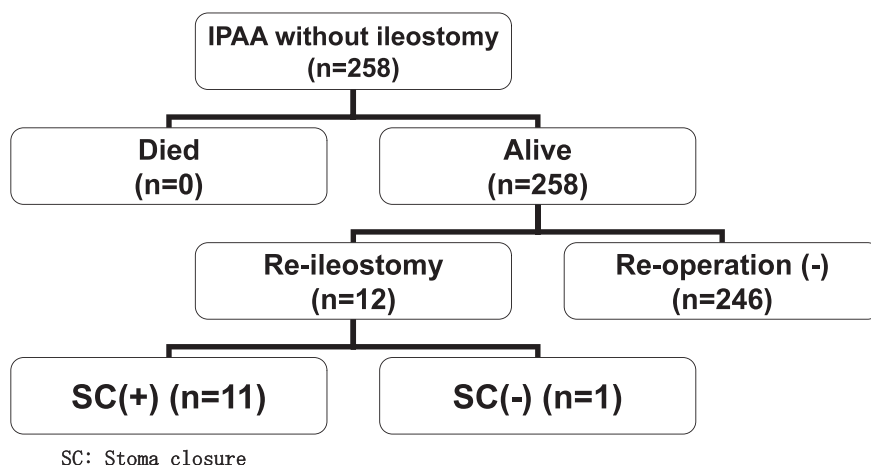


Fig. 5 Outcomes of patients who underwent IPAA without ileostomy as the initial operation. SC, stoma closure.

Table 5 Early postoperative pouch functional rates

Initial operation	Total colectomy (n = 96)	IPAA with ileostomy (n = 421)	IPAA without ileostomy (n = 258)
Postoperative deaths (%)	6 (6.3%)	4 (1.0%) ^a	0 (0) ^b
No. of pouch operations	78	417	258
No. functional pouches	75	409	257
Early postoperative pouch functional rate	96.2%	98.1%	99.6%

^aSignificant difference between total colectomy and IPAA with ileostomy groups.

^bSignificant difference between total colectomy and IPAA without ileostomy groups.

IPAA, ileal pouch anal anastomosis.

functional outcome.^{5,6} In 1997, we changed our mucosectomy procedure from using an electrocoagulator to an HS.⁴ The mechanical cutting effect of an HS is most easily achieved in anorectal mucosa with high protein density. A mucosectomy requires cavitation cutting and tissue plane separation without injuring the remaining sphincters. We have already reported that introduction of this technique has enabled us to perform IPAA without ileostomy in patients with UC.^{7,8}

Controversy remains whether to perform a mucosectomy with a hand-sewn anastomosis or a stapled anastomosis in UC patients, with much of the current debate centered on the probable functional advantage of retaining the anal canal mucosa versus the disadvantage of potential malignancy.⁹⁻¹² Previously, we reported that the incidence of dysplasia in the mucosectomy area was 4.4%, and the risk for dysplasia in that area was significantly associated with a disease duration of more than 10 years and age at surgery more than 40 years.¹³ Therefore, we determined that it is better to consider

a mucosectomy for such patients, yet also considering the postoperative functional results and prognosis in patients who are more than 60 years old.

Herein, we reviewed 775 consecutive patients with UC who underwent IPAA with mucosectomy using an HS from November 1999 to December 2009. We were especially interested in the operative indications, operative procedures, postoperative complications, and postoperative long-term results. Surgery for UC can be used either for emergency or elective operations. Indications for emergency surgery in our series included failed medical treatment for patients with acute severe colitis, toxic colonic dilatation, perforation, and severe bleeding. Acute severe colitis requires hospital admission and intensive medical treatment, and its management involves monitoring of vital signs and bowel function, as well as treatment of malnutrition and toxicity, which are usually present to some degree. Water and electrolyte depletion, and anemia should

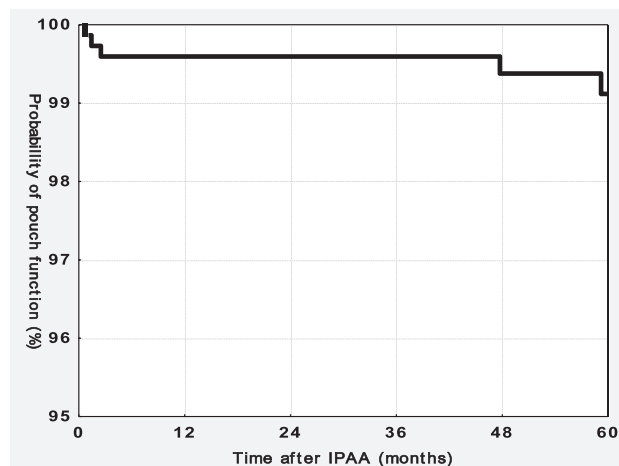


Fig. 6 Cumulative pouch functional rates for all patients. The pouch functional rate for all patients with a functioning ileal pouch after 5 years was 99.1%.

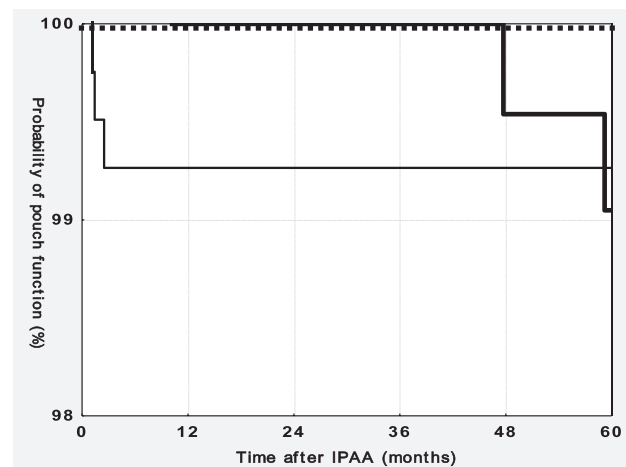


Fig. 7 Cumulative pouch functional rates for IPAA patients based on initial operation. After 5 years with a functioning ileal pouch, the rates for the total colectomy, IPAA with ileostomy, and IPAA without ileostomy groups were 100%, 99.3%, and 99.0%, respectively.

be corrected, in combination with specific anti-inflammatory treatment including high dose intravenous steroids. The decision for surgery should be made in joint consultation with a gastroenterologist and surgeon, based on the response to medical treatment.

In the present study, the mortality rate in the total colectomy group was higher than that in the other 2 groups. Furthermore, the preoperative characteristics of that group were short duration of disease and few total, but large daily, steroid doses. Thus, the patients who underwent a total colectomy as the initial operation showed acute disease exacerbation with a short duration of disease. We consider that it is important to maintain close cooperation between the attending gastroenterologist and surgeon for these patients.

In conclusion, in the present series, we found low operative mortality, and acceptable rates of early and late complications in patients with UC who underwent a restorative proctocolectomy and IPAA using an HS.

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