



Long-term outcomes following restorative proctocolectomy ileal pouch-anal anastomosis in pediatric ulcerative colitis patients: Multicenter national study in Japan

Hiroki Ikeuchi¹  | Motoi Uchino¹ | Akira Sugita² | Kitaro Futami³ | Kouhei Fukushima⁴ | Keisuke Hata⁵ | Kazutaka Koganei² | Masato Kusunoki⁶ | Keiichi Uchida⁶ | Riichiro Nezu⁷ | Hideaki Kimura⁸ | Kenichi Takahashi⁹ | Michio Itabashi¹⁰ | Hitoshi Kameyama¹¹ | Daijiro Higashi³ | Fumikazu Koyama¹² | Takeshi Ueda¹² | Tsunekazu Mizushima¹³  | Yasuo Suzuki¹⁴

¹Department of Inflammatory Bowel Disease Surgery, Hyogo College of Medicine, Nishinomiya, Hyogo, Japan

²Department of Inflammatory Bowel Disease, Yokohama Municipal Citizen's Hospital, Yokohama, Kanagawa, Japan

³Department of Surgery, Fukuoka University Chikushi Hospital, Chikushino, Fukuoka, Japan

⁴Department of Surgical and Molecular Pathophysiology, Tohoku University Graduate School of Medicine, Sendai, Miyagi, Japan

⁵Department of Surgical Oncology, The University of Tokyo, Tokyo, Japan

⁶Department of Gastrointestinal and Pediatric Surgery, Mie University Graduate School of Medicine, Tsu, Mie, Japan

⁷Department of Surgery, Nishinomiya Municipal Center Hospital, Nishinomiya, Hyogo, Japan

⁸Inflammatory Bowel Disease Center, Yokohama City University Medical Center, Yokohama, Kanagawa, Japan

⁹Coloproctology Center, Tohoku Rosai Hospital, Sendai, Miyagi, Japan

¹⁰Institute of Gastroenterology, Tokyo Women's Medical University Hospital, Tokyo, Japan

¹¹Division of Digestive and General Surgery, Niigata University, Niigata, Japan

¹²Department of Surgery, Nara Medical University, Kashihara, Nara, Japan

¹³Department of Therapeutics for Inflammatory Bowel Diseases, Osaka University Graduate School of Medicine, Suita, Osaka, Japan

¹⁴Department of Internal Medicine, Toho University Sakura Medical Center, Sakura, Chiba, Japan

Correspondence: Hiroki Ikeuchi, Department of Inflammatory Bowel Disease Surgery, Hyogo College of Medicine, Nishinomiya, Hyogo 663-8501, Japan (ikeuci2s@hyo-med.ac.jp).

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Abstract

Background: Few studies have investigated surgical outcomes following a colectomy in pediatric patients with ulcerative colitis (UC).

Purpose: This study aimed to determine long-term outcomes in a large cohort of pediatric patients who underwent proctocolectomy with ileal pouch-anal anastomosis (IPAA) for UC.

Methods: Pediatric patients (<17 years old) who underwent surgery at 12 different hospitals in Japan between May 1979 and March 2015 were included in this study. Information was obtained by the use of a questionnaire survey.

Results: There were 113 (53.3%) male and 99 (46.7%) female pediatric patients. The most common indication for elective surgery was failure of medical management, whereas emergency surgery was carried out for fulminant cases. A hand-sewn

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IPAA was used with a mucosectomy in 112 (52.8%), stapled anastomosis in 93 (43.9%), and not specified in 7 (3.3%) patients. Small bowel obstruction and surgical site infection were the most frequent early postoperative complications (POC), whereas pouchitis, small bowel obstruction, and perianal fistula were frequent late POC. The most common late POC was pouchitis, found in 38 (17.9%) of the patients, whereas pouch failure was noted in 11 patients at the latest follow-up examination. Cumulative pouch survival rate after 10 years was 91.7%. There were no significant differences regarding gender or anastomotic procedure in relation to cumulative pouch survival rate.

Conclusion: To avoid pouch failure following an IPAA procedure, it is important to recognize that pouchitis or an anal fistula may lead to this condition in pediatric UC patients.

KEYWORDS

ileal pouch-anal anastomosis, pediatric, pouch failure, pouch functioning rate, ulcerative colitis

1 | INTRODUCTION

Nearly one-third of patients with ulcerative colitis (UC) will ultimately require surgical treatment, with affected children more likely to require surgery as compared to adults.¹ Initially described in 1978 by Parks and Nicholls, ileal pouch-anal anastomosis (IPAA) is now the procedure of choice for patients with UC, including pediatric cases.^{2,3} Following removal of the colon and rectum, IPAA has become the standard restorative surgical treatment for patients with UC.

Although long-term outcomes following a restorative proctocolectomy IPAA procedure in adults with UC are satisfactory, data regarding long-term outcomes in children are limited.^{4,5} As pediatric patients who undergo IPAA are expected to live with their pouch for many years, good long-term outcome information is urgent for providers, as well as for patients and their families to make informed decisions about undergoing IPAA.

The purposes of the present study were to report long-term outcome data obtained from a large cohort of pediatric patients and to determine the incidence of complications associated with IPAA for UC. This report reflects experiences with surgical management of pediatric UC cases in a large regional area of Japan.

2 | PATIENTS AND METHODS

2.1 | Patients and data collection

We sent a questionnaire survey to representative institutions specializing in surgery for inflammatory bowel disease (IBD) as part of a project study carried out under authority of the Surgical Research Group, the Research Committee of IBD, and the Ministry of Health, Labor and Welfare of Japan. Two hundred twelve pediatric patients who underwent a colectomy for UC at 12 different hospitals in

Japan between May 1979 and March 2015 were included in this study. We examined demographics, preoperative disease severity, indications for surgery, type of operation (1-, 2-, or 3-stage), type of IPAA, early postoperative complications, cumulative 10-year pouch functioning rate, late postoperative complications, cause of pouch failure, and death.

2.2 | Definitions

For this study, pediatric patients were defined as those younger than 17 years old. Those who underwent surgery in 1999 or earlier were defined as the early group and those with surgery in 2000 or later as the late group. Postoperative complications (POC) were classified into two categories, early and late. Early POC were defined as a complication that occurred within 30 days after IPAA creation, whereas late POC were those that developed more than 30 days after undergoing a complete restorative proctocolectomy. Major complications were defined as those with a Clavien-Dindo classification of III or higher.⁶ A diagnosis of pouchitis was determined using the Pouchitis Disease Activity Index (PDAI), an instrument commonly used for measuring disease severity in published clinical trials,⁷ with a PDAI score ≥ 7 suggesting a diagnosis of pouchitis. Pouch failure was defined as excision of the ileal pouch or nonreversed diverting ileostomy.

2.3 | Statistical analyses

Descriptive statistics are reported as median values (range) and frequency (percent) for categorical variables. Statistical analyses were carried out using a chi-squared test or Fisher's exact test for categorical variables, and a Mann-Whitney *U* test for continuous variables. Cumulative incidence of pouch survival was estimated and compared between the two groups using Kaplan-Meier life analysis with a log-rank test. Level of significance was set at $P < 0.05$. All statistical

analyses were carried out using JMP version 11 (SAS Institute Inc., Cary, NC, USA).

2.4 | Ethical considerations

All study protocols were approved by the institutional review board of Hyogo College of Medicine (1970), and informed consent and agreement for the use of relevant information were obtained from the guardians of each patient before surgery.

3 | RESULTS

3.1 | Patient characteristics

Of the 212 patients, 113 (53.3%) were boys and 99 (46.7%) were girls. Mean age at the time of surgery was 14 years (range 5-16 years), and mean duration of disease was 23 months (0.3-195 months). One hundred thirty-four underwent an elective colectomy, whereas 78 had an urgent colectomy. None of the examined factors showed a significant difference between the early and late groups. Patient demographics are presented in Table 1.

3.2 | Surgical indications and details

Operative indications for all cases are shown in Table 2. Failure of medical management was the most common indication for elective surgery, whereas emergency surgery was carried out for fulminant cases. Both the early and late groups had similar findings regarding indications. None of the patients had cancer or dysplasia at the time

of operation. Surgical details are outlined in Table 3. Hand-sewn IPAA procedure with a mucosectomy was carried out in 112 (52.8%) and stapled anastomosis in 93 (43.9%), whereas the procedure was not specified in 7 (3.3%). Among the 205 patients in the early group ($n = 41$) who underwent IPAA, 1-, 2-, and 3-stage operations were carried out in 4 (9.8%), 13 (31.7%), and 24 (58.5%), respectively, whereas in the late group ($n = 164$), these were carried out in 29 (17.7%), 96 (58.5%), and 39 (23.8%), respectively. Thus, a 3-stage operation was most frequently done in the early group, whereas a 2-stage operation was most frequently done in the late group.

3.3 | Postoperative complications

Details of early POC cases are shown in Table 4. Small bowel obstruction and surgical site infection were the most frequent early POC noted. In addition, 22 (45.8%) patients in the early group and 79 (48.2%) in the late group had early POC ($P = 0.87$), with major complications seen in 3 (13.6%) and 12 (15.2%) in the early and late groups, respectively ($P = 0.86$). These cases are shown in Table 5, in which pouchitis, small bowel obstruction, and perianal fistula were frequent, with the most common late POC found to be pouchitis in 38 (17.9%) patients. None of the patients had their final diagnosis changed to Crohn's disease (CD), although biologics were given to 3, because their anal findings strongly suggested CD. None of these 3 patients underwent an ileostomy.

3.4 | Pouch survival rate

Mean postoperative follow-up period in the present study was 53.4 months (0.3-317 months). Pouch failure occurred in 11 patients by the time of the final follow-up examination, with 3 of those undergoing pouch excision with a permanent ileostomy and 8 a diverting ileostomy without excision of the pouch. Kaplan-Meier analysis showed that the rate of pouch survival was 91.7% after 10 years in these patients (Figure 1).

Cumulative pouch survival is shown in Figure 2. The cumulative rate after 10 years was 93.2% in boys and 90.1% in girls, with no significant difference between the genders ($P = 0.35$). Cumulative

TABLE 1 Demographics of 212 pediatric patients who underwent colectomy for ulcerative colitis

Characteristic	Total n = 212 (%)	Early group n = 47 (%)	Late group n = 165 (%)	P-value
Gender				
Male	113 (53.3)	23 (48.9)		0.51
Female	99 (46.7)	24 (51.1)		
Age at the time of surgery (y)	14 (5-16)	14 (6-16)	14 (5-16)	0.27
Duration of disease (mo)	23 (0.3-195)	24 (1-195)	22 (0.3-159)	0.15
Preoperative severity				
Mild	35 (16.5)	6 (12.8)	29 (17.6)	0.87
Moderate	88 (41.5)	21 (44.7)	67 (40.6)	
Severe	81 (38.2)	19 (40.4)	62 (37.6)	
Fulminant	7 (3.3)	1 (2.1)	6 (3.6)	
Unknown	1 (0.5)	0 (0)	1 (0.6)	
Emergency operation	78 (36.8)	16 (34.0)	62 (37.6)	0.48

TABLE 2 Indications for surgery in 212 pediatric patients who underwent colectomy for ulcerative colitis

	Total n = 212 (%)	Early group n = 47 (%)	Late group n = 165 (%)
Elective surgery	134 (63.2)	31 (66.0)	103 (62.4)
Medical intractability	131	28	103
Side-effect of steroid	3	3	0
Emergency surgery	78 (36.8)	16 (34.0)	62 (37.6)
Fulminant type	48	11	37
Severe bleeding	21	5	16
Toxic megacolon	5	0	5
Perforation	4	0	4

TABLE 3 Surgical details in 212 pediatric patients who underwent colectomy for ulcerative colitis

		1-stage	2-stage	3-stage
Ileal pouch-anal anastomosis				
Mucosectomy + hand-sewn anastomosis	112 (52.8%)	4	58	50
Stapled anastomosis	93 (43.9%)	29	51	13
Other operations				
Ileorectal anastomosis	7 (3.3%)			
Ileorectal anastomosis	5			
Total colectomy	2			

TABLE 4 Early postoperative complications in 212 pediatric patients who underwent colectomy for ulcerative colitis

Complication	Total n = 212 (%)	Early group n = 47 (%)	Late group n = 165 (%)
Bowel obstruction			
Small bowel obstruction	43 (20.3)	9 (19.1)	34 (20.6)
Outlet obstruction (stoma)	8 (3.8)	0 (0)	8 (4.8)
Surgical site infection			
Wound infection	29 (13.7)	7 (14.9)	22 (13.3)
Intra-abdominal or pelvic abscess	4 (1.9)	1 (2.1)	3 (1.8)
Anastomotic leakage	9 (4.2)	2 (4.3)	7 (4.2)
Rectal bleeding	3 (1.4)	1 (2.1)	2 (1.2)
Pneumonia	3 (1.4)	2 (4.3)	1 (0.61)
Intra-abdominal bleeding	2 (0.94)	2 (4.3)	0 (0)
Convulsions	2 (0.94)	0 (0)	2 (1.2)
Adrenal insufficiency	2 (0.94)	2 (4.3)	0 (0)
Others	10 (4.7)	1 (2.1)	9 (5.4)

TABLE 5 Late postoperative complications (>30 d postoperative)

Complication	Total n = 212 (%)	Early group n = 47 (%)	Late group n = 165 (%)
Pouchitis	38 (17.9)	5 (10.6)	33 (20.0)
Bowel obstruction			
Simple ileus	36 (17.0)	10 (21.3)	26 (15.8)
Strangulated ileus	5 (2.4)	2 (4.3)	3 (1.8)
Fistula (perianal)	28 (13.2)	8 (17.0)	20 (12.1)
Anastomotic stricture	9 (4.2)	2 (4.3)	7 (4.2)
Cuffitis	4 (1.9)	1 (2.1)	3 (1.8)
Intra-abdominal abscess	2 (0.94)	0 (0)	2 (1.2)
Others	8 (3.8)	4 (8.5)	4 (2.4)

pouch survival rates in the hand-sewn and stapled anastomosis groups after 10 years were 87.6% and 97.6%, respectively, which was not significantly different ($P = 0.23$) (Figure 3).

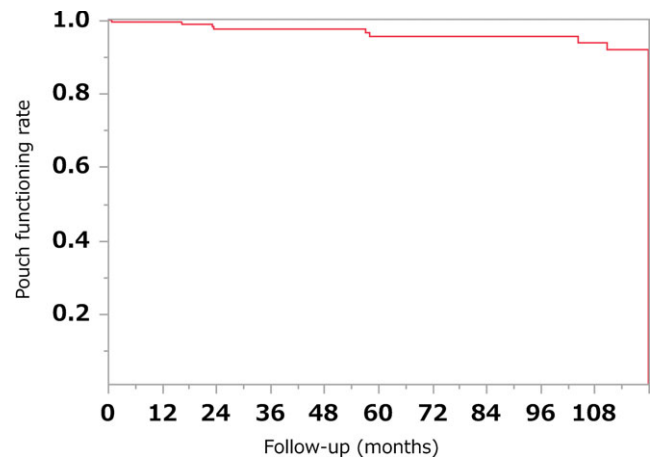


FIGURE 1 Pouch functioning rate in pediatric patients. Cumulative rates of long-term pouch function in pediatric patients with ulcerative colitis. The cumulative pouch functioning rate was 91.7% at 10 y after the operation

3.5 | Causes of pouch failure

Ileal pouch-anal anastomosis failure occurred in 11 (5.2%) patients during the follow-up period. Causes of pouch failure were perianal fistula ($n = 4$), pouch-vaginal fistula ($n = 3$), pouchitis + perianal fistula ($n = 2$), pouchitis ($n = 1$), and small bowel torsion ($n = 1$). None of these patients had their diagnosis changed to CD after surgery.

3.6 | Death during follow-up period

Three patients (1.4%) died during the follow-up period. There were no cases of death in the early postoperative period, and none of the 3 deaths during long-term follow up were related to the surgical procedure. Causes of long-term mortality included venous brain

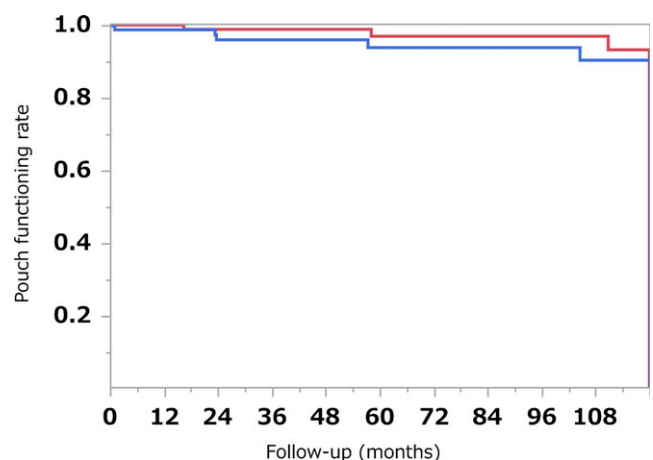


FIGURE 2 Pouch functioning rate in boys and girls. Cumulative pouch functioning rate was 93.2% in boys (red line) and 90.1% in girls (blue line) at 10 y after the operation, which was not significantly different ($P = 0.35$)

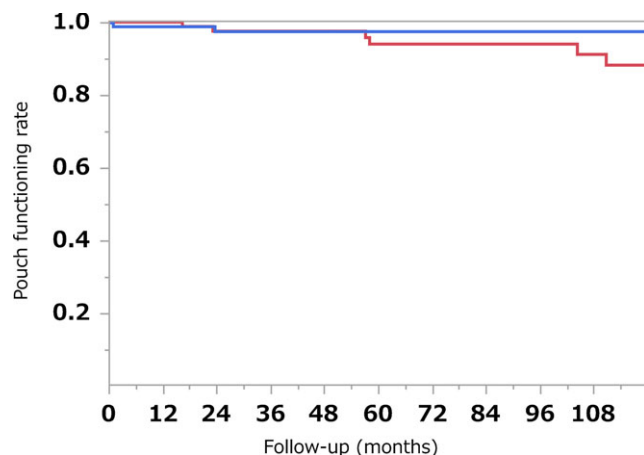


FIGURE 3 Pouch functioning rate in hand-sewn and stapled anastomosis cases. Cumulative pouch functioning rate was 87.6% in the hand-sewn group (red line) and 90.1% in the stapled anastomosis group (blue line) at 10 y after the operation, which was not significantly different ($P = 0.35$). There was no significant difference regarding cumulative pouch functioning rate between anastomotic types ($P = 0.23$)

thrombosis at 23 years after the operation in 1 case, whereas the others are unknown.

4 | DISCUSSION

As compared to adults, pediatric UC patients often have more extensive disease and greater disease severity at diagnosis.^{8,9} Furthermore, risk of colectomy may be higher in pediatric patients, as the reported cumulative colectomy rates at 1, 3, and 5 years after onset are 8%, 15%, and 20%, respectively.^{10–12} Of the available surgical options for UC, total proctocolectomy with IPAA has become the procedure of choice. IPAA can be carried out as a 1-, 2-, or 3-stage procedure using either a hand-sewn or stapled technique for pouch-anal anastomosis, which allows the patient to maintain a near-normal pattern of defecation with reasonable continence following surgery.

In the 1980s to early 1990s, Ozdemir et al¹³ used a mucosectomy with a hand-sewn IPAA method. Following introduction of stapler devices, stapled IPAA became their preferred technique, except in patients with dysplasia or early-stage cancer of the lower rectum. The same trends have been seen in Japanese patients. In the present study, 53% of the investigated pediatric UC patients underwent a mucosectomy with IPAA, and there was no significant difference regarding cumulative pouch survival rate between the hand-sewn and stapled anastomosis groups. Remzi et al¹⁴ noted that as pediatric patients have a long life expectancy, functional outcomes as well as control of neoplastic activities of the anal canal and ileal reservoir are important.

In reports of adult patients, long-term pouch failure rates vary between 5% and 7%.¹⁵ The pediatric patients in a series reported by Ozdemir had a pouch failure rate of 9% after a mean follow-up period of 9 years.¹³ UC severity is associated with younger

age at diagnosis; thus, its negative effects on growth and development may be important factors causing the higher pouch failure rate in the pediatric age group. Hirata et al¹⁶ presented similar results for Japanese patients, with the cumulative rate of pouch failure at 10 years after a restorative proctocolectomy significantly higher in pediatric (9.5%) as compared to adult (2.1%) UC cases ($P < 0.01$). Although pouch failure following a restorative proctocolectomy is more common in pediatric UC patients as compared to adults, these poor results do not suggest that surgery should be avoided. Nevertheless, proper timing for carrying out a surgical procedure is necessary for pediatric patients because of the higher level of disease activity and extent of colitis as compared to adults with UC.

Notably, in the present study, a significantly higher population of girls had complications related to fistulae development and obstruction as compared to boys. Shannon et al¹⁷ speculated that anatomical differences between the genders, in particular, the presence of the vagina, caused an increased risk for fistula formation. Moreover, Hirata et al¹⁶ reported that female gender was an independent risk factor for pouch-related complications, although not related to pouch failure. In the present study, 3 of 11 cases of pouch failure were associated with a pouch-vaginal fistula.

Shannon et al¹⁷ reported that pouch failure was the most common factor associated with change in diagnosis of CD patients with fistula development. Similar to adults, long-term pouch success in pediatric patients with CD is much lower than in pediatric patients without CD; thus, an IPAA is not recommended for children known to have CD.^{3,14,17} Unfortunately, a diagnosis of CD is often not seen until the postoperative period. In the present study, none of the patients had their final diagnosis changed to CD, although biologics were given to 3, because their anal findings strongly suggested CD. It is difficult to make a proper diagnosis prior to pouch excision, although a change in diagnosis from UC to CD is a major risk factor for pouch failure. Therefore, treatment with biologics may be necessary to avoid pouch failure in patients with a perianal fistula regardless of diagnosis.

Pouchitis has been reported to be the most frequent complication associated with IPAA in both children and adults,^{1,18,19} although frequency differs significantly among studies, ranging from 25% to 73%.^{19–21} In the present study, pouchitis was the most common late POC and was found in 38 (17.9%) of the investigated patients. Moreover, of 11 who showed pouch failure, 3 cases had pouchitis involvement. Establishment of therapy for refractory pouchitis is an important topic for future investigations.

Some reports of elderly patients have noted that the rate of perioperative mortality in cases of emergency surgery is high,^{22,23} whereas there were no perioperative deaths during emergency surgery in the present cases.

Limitations of the present study include its retrospective design and use of a questionnaire to obtain data. Additionally, the 35-year time period may have introduced confounding variables, such as advances in technology and improvements in medical management including biologic therapy.

In conclusion, even though proctocolectomy may offer a cure for patients with UC, morbidity associated with this operation must be considered, especially in pediatric cases. To avoid pouch failure after a restorative proctocolectomy, it is important to note that pouchitis and an anal fistula may lead to pouch failure in pediatric patients with UC.

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ORCID

Hiroki Ikeuchi  <http://orcid.org/0000-0001-9144-5782>

Tsunekazu Mizushima  <http://orcid.org/0000-0002-0825-6823>

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