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Surgical trend including minimally invasive surgeries for ulcerative colitis in the COSUC study: the largest multicenter cohort study in Japan

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Abstract

Background The number of patients with ulcerative colitis (UC) is increasing rapidly in Asia. No large study has evaluated the clinical outcomes of hand-sewn ileal pouch-anal anastomosis (IPAA). This study aimed to create a large database of the surgical outcomes of UC, present the trends of surgical procedures, and evaluate the impact of minimally invasive procedures on UC.

Methods Data of patients first treated from 2005 to 2019 were collected; two-staged surgery data were extracted, and minimally invasive surgery (MIS) and open surgery (OS) outcomes were compared using propensity-score matching.

Results The data of 1558 cases were selected as the main analysis set. The number of surgical cases of UC has been increasing, with increasing proportion of MIS cases (2005: 43%, 2019: 84%). The median age of the patients increased in these 15 years (39.5–56 years old). Of 873 patients who underwent two-staged surgery, after 3:1 matching, 408 MIS and 176 OS cases were compared. Hand-sewn anastomoses were performed in 293 MIS (72.0%) and 142 OS-IPAA (80.7%) cases. The proportion of early complications (≥ Grade 3) did not vary between the two groups. Intraoperative blood loss was lower and blood transfusions were less frequent in the MIS group.

Conclusions The proportion of MIS for UC has rapidly increased over the past 15 years. The total number of MIS and OS complications did not vary significantly between the groups. The short-term advantages of MIS include reduced blood loss and less necessity for blood transfusions.

Keywords Ulcerative colitis · Minimally invasive surgery · Ileal pouch-anal anastomosis · Hand-sewn anastomosis

In recent years, the number of patients with ulcerative colitis (UC) has been rapidly increasing; furthermore, the registered number of patients has doubled in the past 10 years in Japan (2004–2014) [1, 2]. Although advances in drug development have reduced the proportion of patients requiring surgical procedures, a number of patients with UC still require surgical management [3, 4].

Laparoscopic colectomy, which was first introduced in 1992 by Jacobs [5], has been implemented worldwide and has emerged as one of the standard procedures for the management of colorectal cancer [6–8]. Laparoscopic total colectomy was reported in 1992 [9, 10]. Minimally invasive surgeries (MISs) also include Hand-assisted laparoscopic procedures [11, 12]. Recently, the proportion of MIS, including laparoscopic, hand-assisted, robotic, and trans-anal total mesorectal excision approaches, has been increasing, and

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the indications for MIS include severe and emergent disease [13–16].

Proctocolectomy and ileal pouch-anal anastomosis (IPAA) are standard procedures for surgical management of UC. In Japan, many surgeons prefer hand-sewn anastomoses; however, stapled IPAA is usually performed in Western countries [17]. For better oncological outcomes and need for follow-up, hand-sewn anastomosis is preferred; however, stapled anastomosis may be considered to ensure better functional outcomes [18–20].

Lesser postoperative inflammatory response, quicker recovery, and better quality of life are observed with MIS for UC when compared with open surgery (OS) [21, 22]. Considering the postoperative complications, although MIS resulted in fewer complications in many studies, few studies have reported greater complications with MIS than those with OS [23–25]. The evidence obtained through systematic reviews was considered insufficient owing to the small sample size of the included studies [16, 24]. Moreover, the comparison cases included nearly all stapled IPAA cases; thus, no reliable data including hand-sewn IPAA exist.

Thus, our study aimed to create a large database of surgical outcomes of UC, including hand-sewn IPAA, to present the trends of surgical procedures in Japan and the impact of minimally invasive procedures on UC. We collected more than 1000 cases from 48 institutes in Japan, including hand-sewn IPAA cases. We used a study database to determine the treatment trends in Japan and efficacy of MIS for UC.

Materials and methods

This study included patients with UC who underwent open or laparoscopic (including robotic) surgery at 48 institutions that participated in the Japan Society of Laparoscopic Colorectal Surgery between January 2005 and December 2019. The study was named as the clinical outcome of surgery for ulcerative colitis (COSUC Study). Elective and emergency cases were included. Patients who did not want to participate and those who only underwent stoma creation surgery were excluded. After approval by the Central Ethics Committee of Kyoto University (R3679) and each institute, all resection procedures were collected as an entire cohort, and the annual trends of the patients' background and surgical procedures were described. The demographic and clinicopathological data of consecutive patients were retrospectively collected, including the cause of the operation, American Society of Anesthesiologists physical status (ASA-PS) classification, steroid and immunosuppressive drug use, preoperative blood test results, operative time, blood loss, intraoperative complications, length of hospital stay, postoperative complications, and pathological results. All case report forms were gathered online using the RED Cap Electronic Data Capture system [26]. Emergency cases were defined as urgent (< 24 h) or semi-urgent (< 7 days).

Subsequently, IPAA cases were chosen, and MIS-IPAA and OS-IPAA were compared using propensity-score matching. Three stage operations were excluded because of the comparison. The primary outcome was the proportion of patients with early postoperative complications. Early postoperative complications were defined as adverse events occurring postoperatively until the date of discharge. Complications were graded according to the Clavien–Dindo (CD) classification, and Grade III complications were determined as the primary outcome. Other postoperative and intraoperative complications, operative time, intraoperative blood loss, postoperative hospital stay, fasting period, and blood infusion rates were also evaluated. In this study, stoma outlet obstructions treated only with tube insertion through the stoma were graded as Grade II.

Surgical procedure

All the procedures including choice of approach were chosen by each surgeon and written informed consent was made by each patient. Laparoscopic approach was opted frequently in recent cases. In most institutions, IPAA with hand-sewn anastomosis was opted for as first choice procedure, and IPAA with stapled anastomosis was opted for when the surgeon judged hand-sewn challenging. If IPAA as deemed challenging owing to oncological reasons or the length of small mesentery, eternal stoma creation was chosen.

Statistical analysis

Case matching was performed using the propensity score of eight factors: sex, age, body mass index, history of abdominal operations, preoperative albumin levels, ASA-PS, preoperative steroid/immunosuppressive drug use, and hospital volume, as prescribed in the protocol. High-volume centers were defined as institutes that registered more than 50 patients with IPAA as 1st operation. Because the number of cases was skewed, a 1:3 variable ratio matching was chosen. Greedy nearest-neighbor matching without replacement within a caliper was used. According to Austin [27], the size of the caliper was set to 0.2 of the standard deviation of the logit of the estimated propensity score. Unmatched patients were excluded from the study.

All the statistical analyses of the primary and secondary endpoints were performed on matched paired patients. Categorical variables were analyzed using Fisher's exact test

or the X^2 test. Continuous variables were analyzed using t tests. All P values were two-sided, with values < 0.05 considered statistically significant. Propensity-score matching was performed using the SAS version 9.4. All other analyses were performed using JMP pro 17.0.0 (SAS Institute, Cary, NC, USA).

Sample sizes were calculated according to previous studies [28, 29]. The proportion of postoperative complications greater than CD grade ≥ III after OS-IPAA was estimated to be 10% and that after MIS-IPAA was estimated to be 5%. Based on the Chi-squared test with a significance level of 0.05 and a power of 0.80, the required sample size was estimated to be 936 (OS: MIS = 1:2).

Results

Data were collected from 1565 patients from 48 institutions. Seven patients were excluded based on the inclusion criteria. The number of surgeries for UC gradually increased (68 cases in 2005 and 126 cases in 2019), and the proportion of MIS cases rapidly increased (29/68 in 2005 to 106/126 in 2019) (Fig. 1). The proportion of MIS at each institute varied from 0 to 100 percent, with a median proportion of 80% (Supplemental Digital Content 1). Although the proportion of males did not change in these 15 years, the median age of the operated patients increased (from 39.5 to 56 years old) in these 15 years (Fig. 2a, b). Despite no change in the usage of steroids, the use of immunosuppressive drugs has been increasing since 2007, and the proportion of UC-associated neoplasm increased from 16 to 36% (Supplemental Digital Content 2a, b and Supplemental Digital Content 3). The proportion of urgent and semi-urgent cases also increased from 28 to 44% (Supplemental Digital Content 4). MIS-IPAA was the procedure most commonly performed in elective cases, whereas OS-total colectomy was the most commonly performed procedure in urgent cases. MIS has also been performed in several semi-urgent cases. In urgent cases, 78 patients (33%) underwent MIS (Supplemental Digital Content 5). The proportion of postoperative complications of CD grade III or higher after the first operation slightly decreased annually (27.9–14.3%) (Supplemental Digital Content 6). Eight patients died during the perioperative period of the first operation. Among the patients, seven underwent emergency surgery; none had undergone IPAA.

Propensity-score matching was performed using these factors in the comparison cohort. The number of MIS-IPAA and OS-IPAA cases was 689 and 184, respectively. After 3:1 variable ratio matching, 408 MIS-IPAA and 176 OS-IPAA patients were chosen as the comparison cohorts (Fig. 3). In the original cohort, the age of patients with MIS-IPAA was higher (43, interquartile range [IQR] 31–58 and 39, 28–53 years old, respectively), the proportion of patients with high ASA-PS scores in the MIS-IPAA group was lower (6.4% vs. 12.6%), and the proportion of patients with high-hospital volume in the MIS-IPAA group was lower (42.5%) than that in the OS-IPAA group (76.1%). After matching, the bias improved (Table 1). As the number of urgent and semi-urgent cases was small, this factor was not used for PS matching.

The operative results are shown in Table 2. Hand-sewn anastomoses were performed in 293 MIS cases (72.0%) and 142 OS-IPAA cases (80.7%). The operative time for MIS-IPAA was longer than that for OS-IPAA. Blood loss was less in the MIS-IPAA group than in the OS-IPAA group. No significant difference was observed in the intraoperative complications between the two groups (1.0% vs. 0.6%). The conversion rate of MIS-IPAA to open surgery was 3.2%. Six patients (1.5%) with MIS and five patients (2.8%) with OS-IPAA underwent one-stage surgery without stoma formation. Other patients who received IPAA with a temporary stoma, 24 patients (5.9%) with MIS, and 10 patients (5.7%) with OS-IPAA could not undergo stoma-closure surgery.

The short-term results are summarized in Table 2. The total proportions of Grade III or higher postoperative complications of MIS-IPAA and OS-IPAA were 16.9% and 14.2%, respectively. No statistically significant difference was observed between the two groups ($p = 0.41$). The proportion of complications after MIS-IPAA was 23.1%, 16.8%, and 14.3% in the early, middle, and recent periods, respectively. On the other hand, those after OS-IPAA in each period were 13.3%, 14.3%, and 18.8%, respectively. Re-operations due to postoperative complications were performed for 11 patients of OS (6.3%) and 22 patients of MIS (5.4%). No perioperative deaths occurred in either group. Perioperative blood infusion was needed for 9.1% of patients in the MIS-IPAA group, whereas it was needed for 14.8% of those in the OS-IPAA group. The median fasting period was 4 (IQR 3–6) days and 3 (2–5) days in the MIS and OS groups, respectively. Grade II or higher postoperative complications occurred in 41.7% of MIS-IPAA cases and 39.2% of OS-IPAA cases. The incidences of Grade III or higher complications are shown in Table 3. The frequencies of surgical site infection, intra-abdominal abscesses, and pneumonia were similar. The proportion of anastomotic leakage was slightly lower and that of bowel obstruction was slightly higher in the MIS-IPAA group.

Discussion

In this cohort study, more than 1500 patients' surgical data, including those with hand-sewn IPAA, were collected [17]. The number of patients with UC is rapidly increasing, and the number of surgical cases has also gradually increased.

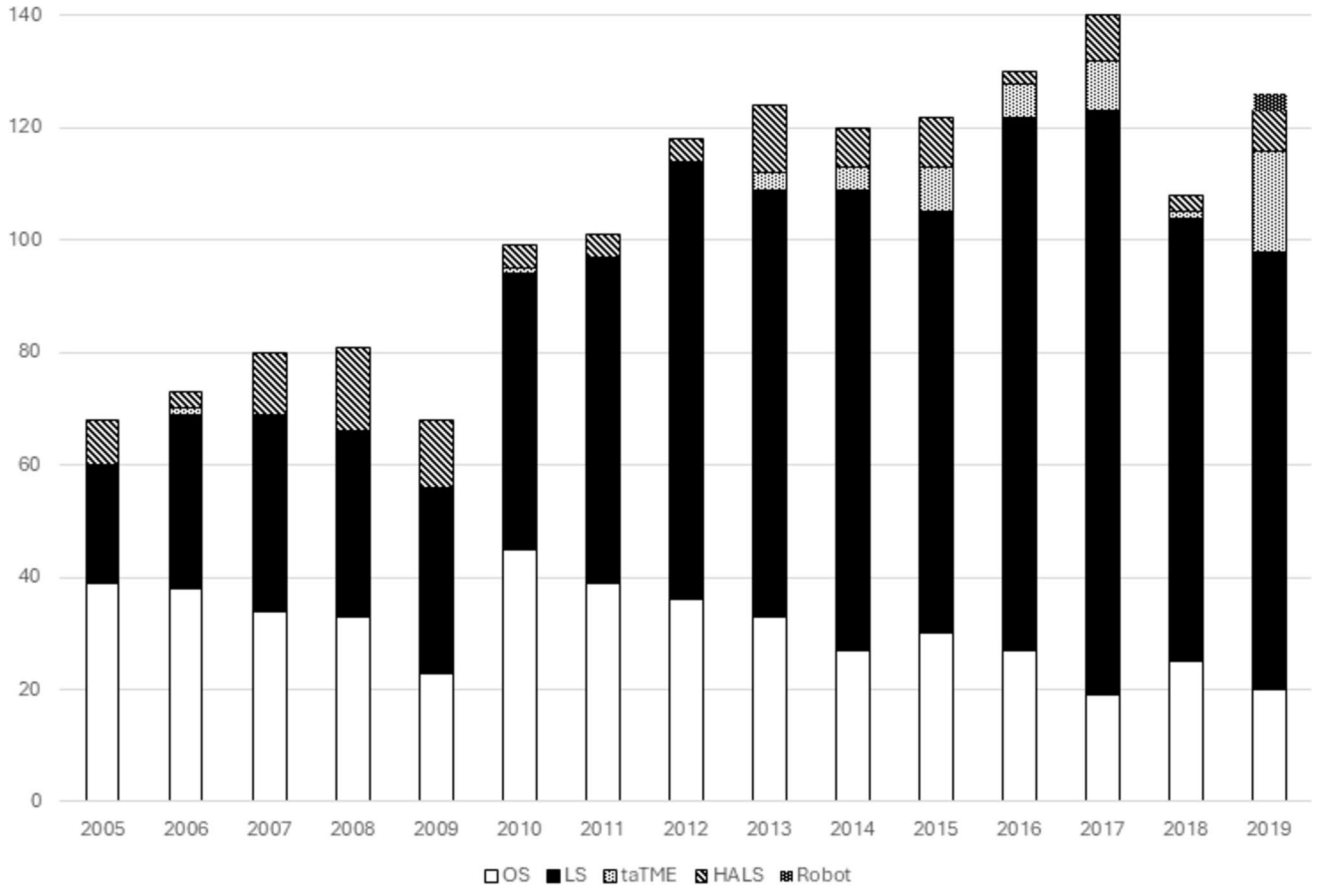

Fig. 1 Trend of surgical approach

The number of patients undergoing surgical procedures has changed owing to advancements in the development of drugs and laparoscopic surgery. The proportion of male patients was approximately 60%, and the proportion did not change in these 15 years; however, the median age of patients who underwent surgical procedures clearly increased in these 15 years. This may be attributed to the trend observed in all patients with UC in Japan. One reason is advances in drug therapy for UC, and another is the increase in cases of elderly onset UC. Komoto et al. [30] reported that elderly onset (> 65 years old) are likely to require hospitalization or UC-related surgery using big data in Japan. During these 15 years, the proportion of minimal invasive surgery rapidly increased from 43 to 84% in this study. A report from US with 6184 patients treated from 2005 to 2019 demonstrated that 2555 underwent MIS (41.3%); however, the trend was not presented [31]. Whereas, using NSQIP data, the proportion of MIS-IPAA with total proctocolectomy was reported as 77.7% from 2016 to 2020 [32].

Several studies have reported on the postoperative complications following surgery for UC. Fleming et al. [33] reported that the laparoscopic approach was associated with lower rates of major and minor complications in patients with IPAA. Singh et al. [24] reported that the laparoscopic approach was associated with a lower incidence of wound infections. Cai et al. [25] reported laparoscopic surgery to be an independent protective factor against short-term complications. Habermann et al. [31] also reported MIS as lower risk of morbidity compared with OS. However, several review articles have reported similar incidences of postoperative complications between MIS and OS[28, 34]. Our results also demonstrated no differences in the postoperative complications between the MIS and OS groups. Although the difference was not statistically significant, the proportions of complications after MIS-IPAA gradually decreased, which may be attributed to the learning curve of MIS surgery. The decrease could not be seen after OS-surgery. Thus, the proportion of complications after MIS-IPAA could be lower than that after OS-IPAA in the future. Although the MIS-IPAA group had a longer operative time, the blood loss was lower in the MIS-IPAA group than in the OS-IPAA group. Severe bowel obstruction is more likely to occur after MIS-IPAA than after OS. Anastomotic leakage occurred more frequently after OS-IPAA. The length of postoperative hospital stay was similar between the two groups; however, the fasting time

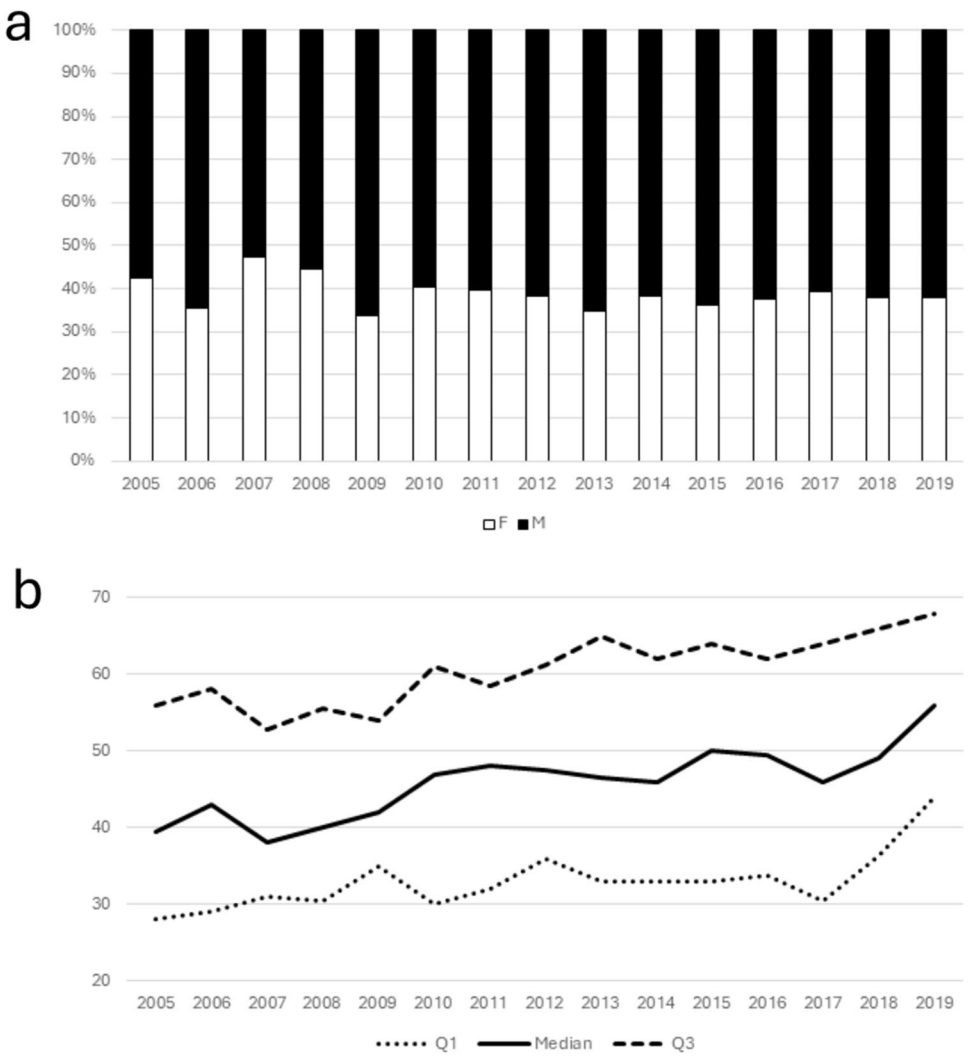

Fig. 2 **a** Transition of sex ratio. **b** Transition of age structure

was shorter in the OS-IPAA group, which may be attributed to institutional bias. When stratified by institution, fasting time was similar or slightly shorter in the MIS-IPAA group.

Based on the results of the preliminary survey (data not shown), the study period was from 2005 to 2019. We compared MIS-IPAA and OS-IPAA; however, the proportion of laparoscopic surgeries for stable UC was 99% in 2020. The second survey revealed that the proportion of MIS cases of UC increased in recent years. As shown in the results, MIS for UC has spread rapidly in Japan, and comparing MIS and OS-IPAA in future patients may be challenging. We performed propensity-score matching at a ratio of 1:3 rather than 1:2 according to the proportions of each procedure.

Fukui et al. [20] demonstrated that the maximum resting anal pressure showed a transient decrease after stapled IPAA but remained low after hand-sewn IPAA. However, hand-sewn IPAA with mucosectomy is ideal in terms of the oncological outcomes. In contrast to most of the previous large studies that included only stapled IPAA, our database includes many cases with more than 70% hand-sewn anastomoses. Long-term outcomes are crucial and should be examined in future studies.

In this study, the incidence of complications was higher than expected; however, no perioperative deaths occurred. The proportion of patients with grade II complications was approximately 40% throughout the study period. This may be attributed to the use of an online detailed clinical report form. In retrospective studies, the incidence of complications tended to be lower than the actual results. We believe that our results are representative of those of real-world data. The length of postoperative hospital stay did not differ between the two groups. A systematic review involving 206 patients demonstrated a similar length of hospital stay; however, the level of evidence was not high due to the small sample size [34]. In the US, hospital stays are generally shorter than those in Japan, and the length of stay after MIS has been reported to be shorter than that after OS [31].

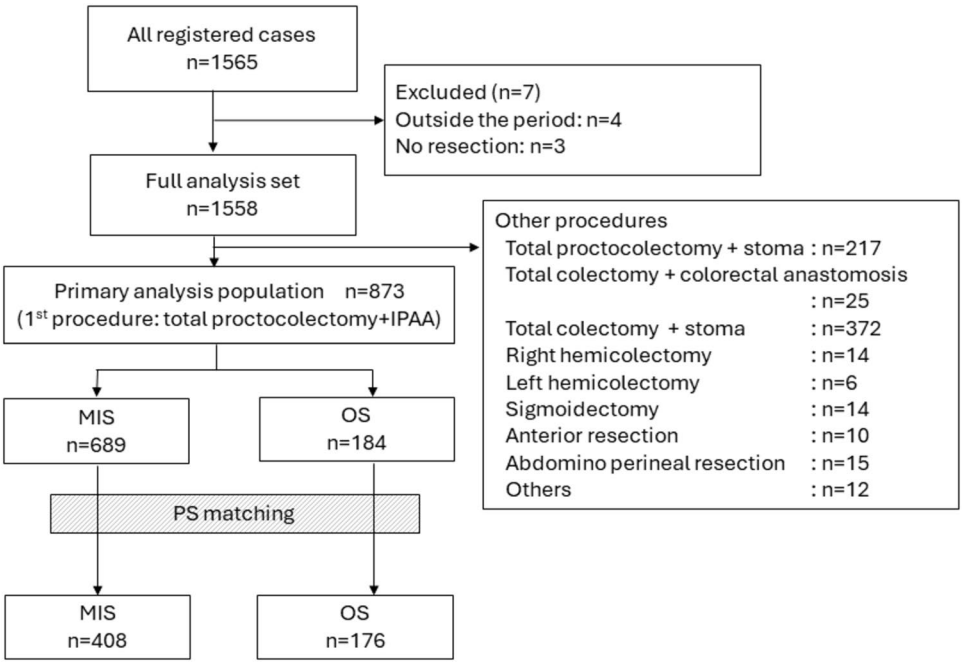

Fig. 3 Patient flow of ileal pouch-anal anastomosis (IPAA) with minimal invasive surgery (MIS) and open surgery (OS) using propensity-score (PS) matching

Table 1 Baseline characteristics in patients undergoing open or laparoscopic IPAA

	Overall					Matched				
Variable	OS (n = 184)		MIS (n = 689)		SMD	OS (n = 176)		MIS (n = 408)		SMD
Sex Male	113	(61.4%)	387	(56.2%)	− 0.14	110	(62.5%)	247	(60.5%)	− 0.04
Age	39	(28–53)	43	(31–58)	0.18	39	(28–53)	42	(30–57)	0.14
BMI	19.7	(17.4–22.5)	20.3	(17.9–22.6)	0.16	19.7	(17.4–22.5)	20.0	(17.6–22.5)	0.06
Previous abdominal operation	11	(6.0%)	57	(8.3%)	0.08	11	(6.3%)	27	(6.6%)	0.02
ASA-PS > = 3	23	(12.6%)	44	(6.5%)	− 0.2	21	(11.9%)	33	(8.1%)	− 0.13
Albumin g/dl	3.6	(3.0–4.1)	3.7	(3.0–4.1)	0.09	3.6	(3.0–4.1)	3.6	(2.8–4.1)	− 0.06
Steroid and Immunosuppressive use	142	(77.6%)	522	(75.9%)	− 0.05	137	(77.8%)	314	(77.0%)	− 0.02
High-volume center IPAA cases > 50	140	(76.1%)	293	(42.5%)	− 0.78	138	(78.4%)	289	(70.8%)	− 0.17
Emergency	12	(6.5%)	17	(2.5%)	− 0.16	9	(5.1%)	11	(2.7%)	− 0.13
CRP	0.4	(0.1–1.5)	0.3	(0.1–1.3)	− 0.05	0.4	(0.1–1.3)	0.4	(0.1–1.6)	0
WBC	7300	(5640–9550)	6500	(5100–8400)	− 0.2	7300	(5655–9625)	6590	(5030–8105)	− 0.25
Hb	11.1	(9.5–13.2)	11.4	(9.9–13.1)	0.04	11.1	(9.5–13.2)	11.1	(9.8–12.9)	− 0.02
lym	1280	(890–1768)	1342	(991–1900)	0.15	1290	(925–1800)	1312	(984–1798)	0.11
UCAN/dysplasia	30	(16.3%)	233	(33.8%)	0.39	29	(16.5%)	110	(27.0%)	0.26
Operative year										
2005–2009	94	(51.1%)	136	(19.7%)	0.93	90	(51.1%)	78	(19.1%)	0.86
2010–2014	74	(40.2%)	255	(37.0%)		70	(39.8%)	155	(38.0%)	
2015–2019	16	(8.7%)	298	(43.3%)		16	(9.1%)	175	(42.9%)	

BMI body mass index, *ASA-PS* American Society of Anesthesiologists physical status, *IPAA* ileal pouch-anal anastomosis, *SMD* standardized mean difference

Upper rows show the variables used for propensity-score matching. Lower rows show other variables

Data are presented as median (interquartile range) for continuous variables, and numbers (%) for categorical variables

Table 2 Intra- and postoperative results

	Intra- and post- operative results				
	OS-IPAA (n = 176)		MIS-IPAA (n = 408)		p-value
Operative time	299	(252–364)	458	(379–547)	< 0.001
Blood loss volume	365	(169–604)	150	(60–280)	< 0.001
Anastomosis procedure					
Hand-sewn	142	(80.7%)	293	(72.0%)	0.027
Stapler	34	(19.3%)	114	(28.0%)	
Stoma	171	(97.2%)	402	(98.5%)	0.26
Conversion			13	(3.2%)	
Intraoperative transfusion	26	(14.8%)	37	(9.1%)	0.042
Intraoperative adverse event (CTCAE v5.0)	1	(0.6%)	4	(1.0%)	0.62
Time to intake	3	(2–5)	4	(3–6)	< 0.001
Postoperative transfusion within 72 h	13	(7.4%)	14	(3.4%)	0.037
Postoperative hospital stay	20	(15–31)	21	(16–32)	0.13
Total complication grade > = 3	25	(14.2%)	69	(16.9%)	0.41
Early period (2005–2009)	12	(13.3%)	18	(23.1%)	
Middle period (2010–2014)	10	(14.3%)	26	(16.8%)	
Recent period (2015–2019)	3	(18.8%)	25	(14.3%)	

Median (IQR)

Continuous variables are compared using the Wilcoxon rank-sum test

Categorical variables are compared using Pearson's chi-square test

Table 3 Frequency of complications

Complications (Grade = > 3)									
Variable		OS (n = 176)				MIS (n = 408)			
		IIIa	IIIb	IVa		IIIa	IIIb	IVa	
Total complications		14	11	0	14.2%	45	19	5	16.9%
Ileus/Bowel obstruction		3	4		4.0%	14	12	2	6.9%
	Adhesion	1	1		1.1%	4	3		1.7%
	Paralytic	2	1		1.7%	10			2.5%
	Internal hernia				0.0%	1		1	0.2%
	Stoma outlet obstruction		2		1.1%		9	1	2.5%
SSI		4			2.3%	10			2.5%
Anastomotic leakage		7	2		5.1%	11	2		3.2%
Intraabdominal Abscess		8	2		5.7%	21	2	1	5.9%
Bleeding		1	1		1.1%	1	2	1	1.0%
Pneumonia					0.0%			1	0.2%

The incidence of anastomotic leakage was 3.2% after MIS-IPAA and 5.1% after OS-IPAA. The anastomosis procedure itself did not differ between the two groups (hand-sewn or stapled anastomosis), and the leakage rate was low, possibly due to the high proportion of hand-sewn anastomoses. Previous studies have analyzed surgical site infections, including anastomotic leaks and wound infections, comparing MIS and OS. The difference between the two groups was reported as either significant or not significant, depending on the study [31, 34]. Reoperation rates after MIS-IPAA and OS-IPAA were 5.4% and 6.3%, respectively, and no mortality was observed in either group in this study. The conversion rate of MIS-IPAA was 3.2%, and these rates were comparable with those of previous reports [32, 35].

Our study demonstrated reduced blood loss and incidence of blood transfusions in the MIS-IPAA group. Perioperative blood transfusion was reported to be a significant factor in postoperative infectious complications in a systematic review [36]. Fiorino et al. [37] reported that the co-diagnosis of iron deficiency anemia in patients with inflammatory

bowel disease was associated with disease progression and a higher related economic burden. Therefore, reduced blood loss and fewer blood transfusions are important for the treatment of UC.

This study had certain limitations. First, owing to the retrospective nature of the study, a certain bias was present in the selection of the surgical approach. Second, because the proportion of laparoscopic surgeries increased annually, it was difficult to compare MIS and OS in the same year. Third, decisions regarding postoperative complications were made by each institution, and the surgeons experience and detailed treatment strategy varied in each institution.

Nevertheless, our study had several strengths. First, our study included many participating institutions. Although the number of patients of each included institute was not large, we were able to collect the 'Real-World' data from 48 institutions; thus, this study can be generalized widely in Japan. Second, the population of hand-sewn anastomoses was high. The surgical technique of anastomosis is similar between MIS-IPAA and OS-IPAA, and many Japanese surgeons choose hand-sewn IPAA. However, the outcomes have not yet been adequately reported until now. Third, we demonstrated the treatment trends in this rapidly changing era. Although the number of patients is increasing, new drugs are being introduced annually.

In conclusion, the treatment trends for UC were demonstrated using large retrospective data in this study. The median age of patients who undergo surgery for UC is increasing rapidly, and the proportion of patients undergoing MIS has been increasing over the past 15 years. The proportion of postoperative complications following MIS-IPAA and OS-IPAA did not differ; however, blood loss and the amount of perioperative blood transfusion were lower in the MIS-IPAA group.

Supplementary Information The online version contains supplementary material available at https://doi.org/10.1007/s00464-025-11758-6.

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Declarations

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