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ORIGINAL ARTICLE

Laparoscopic extraperitoneal colostomy has a lower risk of parastomal hernia and bowel obstruction than transperitoneal colostomy

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Abstract

Purpose Several studies indicate that an extraperitoneal colostomy can prevent the development of a parastomal hernia (PSH) as compared to a transperitoneal colostomy. However, the clinical value of laparoscopic extraperitoneal colostomy, and its influence on bowel obstruction and PSH remain unclear. The present study aimed to clarify the impact of laparoscopic extraperitoneal colostomy on the development of a PSH and bowel obstruction.

Methods This study included 327 consecutive patients who underwent laparoscopic abdominoperineal resection or Hartmann's procedure between January 2013 and December 2019 after fulfilling selection criteria. The incidence of a PSH (Clavien–Dindo classification ≥ grade I) and bowel obstruction (≥ grade IIIa) in the transperitoneal and extraperitoneal route groups were analyzed using univariate and multivariate analysis.

Results The patients were classified into transperitoneal ($n = 222$) and extraperitoneal ($n = 105$) route groups. The patient characteristics, except for body mass index and operative time, were comparable between the groups. A PSH and bowel obstruction occurred more frequently in the transperitoneal than in the extraperitoneal route group (17.1% vs. 1.9% and 15.3% vs. 6.7%, respectively; $p < 0.01$ and $p = 0.03$, respectively). The multivariate analysis showed that age ≥ 70 years, body mass index ≥ 22.4 kg/m^2, and a transperitoneal route were independent risk factors for the development of a PSH, and a transperitoneal route was an independent risk factor for bowel obstruction.

Conclusions The transperitoneal route was identified as a risk factor for the development of both a PSH and bowel obstruction after laparoscopic abdominoperineal resection or Hartmann's procedure.

Keywords Bowel obstruction · Extraperitoneal route · Laparoscopic colostomy · Parastomal hernia · Transperitoneal route

Introduction

An abdominoperineal resection (APR) or Hartmann's procedure (HP) is performed for patients with colorectal tumors to achieve oncological clearance or avoid anastomosis. A permanent sigmoid colostomy or descending colostomy should be performed with careful attention to prevent stoma-related complications in these procedures. A parastomal hernia (PSH) is the most common long-term stoma-related complication, and its incidence ranges from 4.0 to 48.1% [1–12]. Many studies have emphasized the importance of the stoma creation route in preventing PSH [5–12]. The extraperitoneal route was first reported by Goligher in 1958 [5]. Two large meta-analyses found that a colostomy created through the extraperitoneal route was associated with a lower rate of developing PSH than a colostomy created through the transperitoneal route; however, most of these results were based on open surgery cases [6, 7]. In terms of the surgical approach, only one meta-analysis of 378 cases, including seven studies focused on laparoscopic APR and this meta-analysis found that the laparoscopic extraperitoneal route was associated with a lower rate of developing PSH [8]. Fewer studies focused on the surgical approach because of the technical difficulty of creating an extraperitoneal tunnel

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using a non-flexible instrument during laparoscopic surgery [9]. Hamada et al. [10], Leroy et al. [11], and Hino et al. [12] conducted several retrospective comparative studies and demonstrated that a laparoscopic extraperitoneal colostomy significantly reduced the risk for the development of a PSH compared to a laparoscopic transperitoneal colostomy. However, Heiying et al. [13] conducted a randomized controlled trial and observed no significant difference in the risk for developing a PSH between the extraperitoneal route group ($n = 18$) and the transperitoneal route group ($n = 18$). Notably, the number of patients in those studies that focused on laparoscopic surgery was very small ($n = 22$–59) [10–13]. Therefore, the therapeutic benefits of laparoscopic extraperitoneal colostomy remain unclear.

Postoperative bowel obstruction is a frequent surgical complication in colorectal surgery. Regarding bowel obstruction, this complication was not investigated in the above mentioned meta-analysis [6]. Lian et al. [7] analyzed the incidence of post-colostomy bowel obstruction in a meta-analysis and found no significant difference between the transperitoneal and extraperitoneal route groups; however, they only included two studies that had small sample sizes, focused on open surgery. In another meta-analysis by Leroy et al. [11], the incidence of bowel obstruction was not investigated. To date, only a few studies have focused on the incidence of bowel obstruction and analyzed the effect of the route used for stoma creation after APR or HP. Therefore, we analyzed the development of both PSH and bowel obstruction.

It is worthwhile to elucidate the benefits of extraperitoneal colostomy with laparoscopic surgery in terms of postoperative complications, especially PSH and bowel obstruction. Accordingly, we investigated the relationship between the postoperative complications and the route used for stoma creation in laparoscopic surgery in a large number of consecutive patients at a single center.

Methods

Patient selection

The prospectively collected data from 398 consecutive patients who underwent laparoscopic APR or HP at the Cancer Institute Hospital of the Japanese Foundation for Cancer Research between January 2013 and December 2019 were retrospectively analyzed. Laparoscopic surgery included both conventional and robotic-assisted laparoscopic surgery. A descending or sigmoid colostomy was generally selected for stoma creation in laparoscopic APR and HP. The following patients were excluded from this study: (1) those with an ileostomy, ascending colostomy, or transverse colostomy; (2) those who underwent simultaneous open surgery, such as open hepatectomy for liver metastasis; (3) those who underwent operations for diseases other than a primary rectal tumor, such as complications and recurrent diseases; (4) those who underwent colostomy reversal after HP; or (5) those who had no mention of the route used for stoma creation in the surgical records. A total of 327 patients were analyzed in this study. The prospective colorectal database was used to collect information regarding patient characteristics, preoperative assessments, operative characteristics, postoperative complications, and follow-ups. The postoperative complications were evaluated according to the Clavien–Dindo classification system during the follow-up periods [14]. The follow-up data on the complications were extracted from the medical records. PSH was periodically assessed by surgeons or wound, ostomy, and continence (WOC) nurses or computed tomography (CT) during follow-up outpatient visits. Bowel obstruction, defined as a mechanical blockage of intestinal contents by adhesion, hernia, volvulus, and strangulation, was diagnosed based on the clinical findings during the repeat operation for complications or obvious caliber change on CT images in conservative treatment. Paralytic ileus occurs when there is a nonmechanical decrease or stoppage of the flow of intestinal contents and requires conservative treatment. This study was approved by the Institutional Review Board of the Cancer Institute Hospital (protocol no. 2018–1109).

Surgical methods

The preoperative stoma site was marked by a WOC nurse. At his/her discretion, each surgeon performed a transperitoneal or extraperitoneal colostomy during the surgery. For the extraperitoneal route, the peritoneum along the left paracolic gutter was separated from the abdominal wall to make an internal opening for the extraperitoneal tunnel before the skin incision. A circular incision was made on the skin, and the subcutaneous tissues were incised. Next, the anterior rectal sheath was incised with a cross-shaped incision, and the rectus abdominis was separated to expose the posterior rectus sheath. The posterior rectus sheath was carefully dissected so as not to penetrate the peritoneum. The peritoneum was carefully separated from the abdominal wall to create space. The space was then connected to the previously dissected space along the left paracolic gutter to create an extraperitoneal tunnel. The stump of the colon was then pulled through this tunnel (Supplementary Video 1). For the transperitoneal route, both the posterior rectus sheath and the peritoneum were cut longitudinally, and the colon was pulled through this incision. The stump of the colon was incised and then sutured to the skin with eightstitches before concluding the operation.

Statistical analysis

Data were analyzed using the EZR software package version 3.0 (Saitama Medical Center, Jichi Medical University, Saitama, Japan). The categorical variables were analyzed using Fisher's exact test or Chi-square test. The Mann–Whitney *U* test was used to compare the continuous variables between the two groups. The data differences between the groups were considered statistically significant at $p < 0.05$. Potential risk factors detected by univariate analysis with a p-value < 0.1 were then entered into a multivariate logistical model to determine the independent predictors of the occurrence of PSH and bowel obstruction. Subgroup analyses were performed to determine the independent predictors of the occurrence of PSH stratified by body mass index (BMI).

Results

Patient characteristics

Based on the inclusion and exclusion criteria, 327 patients were analyzed in this study (Fig. 1). The demographic data of the patients are presented in Table 1. Conventional laparoscopic surgery was performed in 308 patients (94.2%), and robotic-assisted laparoscopic surgery was performed in 19 patients (5.8%). Laparoscopic APR and HP were performed in 261 patients (79.8%) and 66 patients (20.2%), respectively. There were 222 (67.9%) patients in the transperitoneal route group and 105 (32.1%) patients in the extraperitoneal route group. One patient in the transperitoneal route group and no patient in the extraperitoneal route group underwent an emergency laparoscopic Hartmann's procedure. The median follow-up duration was 43.8 (range, 0.7–76.7) months.

Table 1 compares patient characteristics between the transperitoneal and extraperitoneal route groups. The median BMI was significantly higher (22.9 vs. 22.0, $p = 0.013$), and the median operative time was significantly longer (345.5 vs. 289, $p = 0.0007$) in the transperitoneal route group than in the extraperitoneal route group.

Postoperative complications

Table 2 compares the postoperative complications (Clavien–Dindo classification ≥ grade I) between the transperitoneal and extraperitoneal route groups. All postoperative complications occurred in 147 patients (66.2%) in the transperitoneal route group and 56 patients (53.3%) in the extraperitoneal route group ($p = 0.03$). PSH occurred in 38 patients (17.1%) in the transperitoneal route group and two patients (1.9%) in the extraperitoneal route group ($p = 0.00002$). Bowel obstruction occurred in 34 patients (15.3%) in the transperitoneal route group and seven patients (6.7%) in the extraperitoneal route group ($p = 0.03$). Supplemental Table 1 shows the differences in the development of PSH or bowel obstruction at different time points after surgery between the two groups (Clavien–Dindo classification ≥ grade I). There were no cases of bowel obstruction caused by PSH. The incidence of other stoma-related complications did not differ between the two groups.

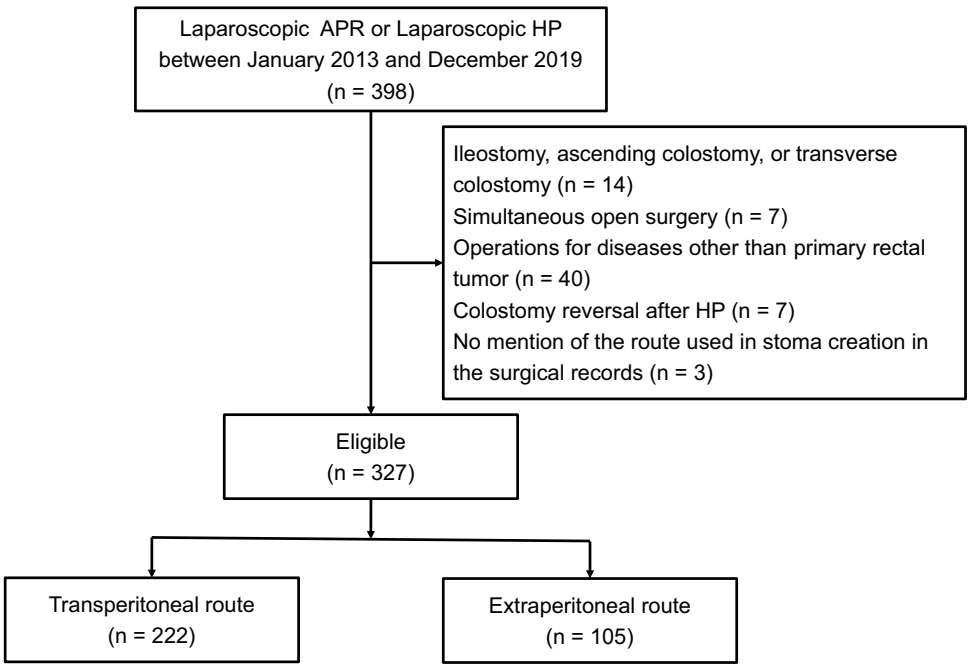

Fig. 1 Flowchart of patient selection. APR, abdominoperineal resection; HP, Hartmann's procedure

Table 1 Comparison of patient characteristics by the route used for stoma creation

	All (n = 327)	*Transperitoneal (n = 222)*	*Extraperitoneal (n = 105)*	*p*
Age, median (range), year	66 (26–91)	67 (6–91)	63 (26–88)	0.14
Sex				
Male	194 (59.3%)	138 (62.2%)	56 (53.3%)	
Female	133 (40.7%)	84 (37.8%)	49 (46.7%)	0.15
BMI, median (range), kg/m^2	22.4 (14.1–39.3)	22.9 (15.3–39.3)	22.0 (14.1–29.1)	0.013
ASA score				
I	72 (22.0%)	50 (22.5%)	22 (21.0%)	
II	247 (75.5%)	169 (76.1%)	78 (74.3%)	
III	7 (2.1%)	3 (1.4%)	4 (3.8%)	
IV	1 (0.3%)	0 (0%)	1 (0.95%)	0.22
Indications				
Sigmoid, rectal, or anal cancer	308 (94.2%)	211 (95.0%)	98 (93.3%)	
Gastrointestinal stromal tumor	5 (1.5%)	2 (0.9%)	3 (2.9%)	
Malignant melanoma	4 (1.2%)	3 (1.4%)	1 (1.0%)	
Neuroendocrine neoplasm	2 (0.6%)	1 (0.5%)	1 (1.0%)	
Others	8 (2.5%)	5 (2.3%)	3 (2.9%)	0.57
History of abdominal surgical history (No/Yes)				
No	228 (69.7%)	152 (68.5%)	76 (72.4%)	
Yes	99 (30.3%)	70 (31.5%)	29 (27.6%)	0.52
Neoadjuvant therapy (No/Yes)				
No	133 (40.7%)	85 (38.3%)	48 (45.7%)	
Yes	194 (59.3%)	137 (61.7%)	57 (54.3%)	0.23
Approaches				
Conventional laparoscopic surgery	308 (94.2%)	208 (93.7%)	100 (95.2%)	
Robotic-assisted laparoscopic surgery	19 (5.8%)	14 (6.3%)	5 (4.8%)	0.80
Procedures				
Abdominoperineal resection	261 (79.8%)	172 (77.5%)	89 (84.8%)	
Hartmann's procedure	66 (20.2%)	50 (22.5%)	16 (15.2%)	0.14
Multivisceral resection				
No	307 (93.9%)	210 (94.6%)	97 (92.4%)	
Yes	20 (6.1%)	12 (5.4%)	8 (7.6%)	0.33
Lateral lymph node dissection				
No	309 (94.5%)	211 (95.0%)	98 (93.3%)	
Yes	18 (5.5%)	11 (5.0%)	7 (6.7%)	0.61
Operative time, median (range), min		345.5 (155–925)	289 (139–766)	0.0007
Blood loss, median (range), mL		60 (0–1,630)	50 (5–580)	0.11
Follow-up duration, median (range), m	43.8 (0.7–76.7)	45.5 (0.8–76.7)	38.0 (0.7–62.8)	0.27

Values represent numbers (percentages) unless indicated otherwise

BMI body mass index, *ASA* American Society of Anesthesiologists

Risk factors for PSH and bowel obstruction

Table 3 shows the results of the univariate and multivariate analyses in terms of PSH. The univariate analysis showed that the potential risk factors for PSH were age ≥ 70 years, BMI ≥ 22.4 kg/ m^2, and the transperitoneal route. Of these, the independent risk factors for PSH were age ≥ 70 (odds ratio = 4.1, 95% confidence interval = 2.0–8.6, $p = 0.0002$), BMI ≥ 22.4 kg/ m^2 (odds ratio = 2.5, 95% confidence interval = 1.1–5.5, $p = 0.02$), and the transperitoneal route (odds ratio = 9.8, 95% confidence interval = 2.3–42.3, $p = 0.002$). In subgroup analyses, the multivariate analyses showed that the potential risk factors for PSH in patients with BMI < 25 kg/m^2 were age ≥ 70 years (odds ratio = 6.0, 95% confidence interval = 1.9–18.9, $p = 0.002$) and the transperitoneal route (odds ratio = 5.3, 95% confidence interval = 1.2–23.7, $p = 0.03$). Table 4 shows the results of the univariate and multivariate analyses in terms of bowel obstruction. The univariate analysis

Table 2 Comparison of the postoperative complications between the two groups (Clavien–Dindo classification, grades I–IV)

	Transperitoneal (n=222)	*Extraperitoneal (n=105)*	*p*
Postoperative complications	147 (66.2%)	56 (53.3%)	0.03
Parastomal hernia	38 (17.1%)	2 (1.9%)	0.00002
Paralytic ileus	10 (4.5%)	7 (6.7%)	0.43
Bowel obstruction	34 (15.3%)	7 (6.7%)	0.03
Wound infection	46 (20.7%)	17 (16.2%)	0.37
Urinary retention/ infection	29 (13.1%)	9 (8.6%)	0.27
Intraabdominal infection	25 (11.3%)	9 (8.6%)	0.56

Values represent numbers (percentages) unless indicated otherwise

showed that the potential risk factors for bowel obstruction (Clavien–Dindo classification ≥ grade IIIa) were history of abdominal surgery and the transperitoneal route. Of these, the route used for stoma creation (odds ratio = 3.1, 95% confidence interval = 1.1–9.3, $p = 0.04$) was an independent risk factor for bowel obstruction based on the multivariate analysis. Supplement Table 2 shows the causes of bowel obstruction (Clavien–Dindo classification ≥ grade IIIb).

Discussion

PSH and bowel obstruction are important complications that cannot be ignored after APR or HP for colorectal tumors. In this study, we analyzed the data of consecutive patients who underwent laparoscopic APR or HP and found that the transperitoneal route was a risk factor for developing both PSH and bowel obstruction. These results suggest that whenever possible, the extraperitoneal route should be recommended, even with laparoscopic surgery. To the best of our knowledge, this is the largest study that focused on investigating and comparing the complications following extraperitoneal and transperitoneal laparoscopic colostomy surgery.

Problems associated with PSH range from mild parastomal discomfort to life-threatening complications such as obstruction, strangulation, or perforation. Therefore, it is vital to prevent the development of PSH. Lian et al. [7] conducted a meta-analysis of 1071 cases and found that the extraperitoneal route was associated with a lower rate of PSH than the transperitoneal route without increasing the risk of other postoperative complications (6.4 vs. 13.3%, odds ratio = 0.4 [95% confidence interval, 0.2–0.7], $p = 0.002$); however, most of the included studies were based on open surgery. In addition, Kroese et al. [6] also performed a meta-analysis of 1048 cases and revealed a lower rate of PSH in the extraperitoneal route group than in the transperitoneal route group (6.3 vs. 17.8%, risk ratio = 0.4 [95% confidence interval, 0.2–0.6], $p < 0.001$); however, only a few included studies that had small sample sizes focused on the laparoscopic approach [10–13]. In the present study, we analyzed 327 patients who underwent laparoscopic surgery and found that a laparoscopic extraperitoneal colostomy significantly reduced the risk of PSH, although there were some problems specifically related to laparoscopic surgery. Our results are similar to those in previous studies that focused on open surgery [6, 7].

The reported risk factors for bowel obstruction include adhesion [15], stoma creation [16–20], and internal hernia [21]. In addition, several studies have identified the presence of an ileostomy [18, 20] or colostomy [19] as risk factors for bowel obstruction. Stoma creation may be associated with an increased incidence of not only adhesion and rotation but also outlet obstruction [22] and internal hernia [21]. For example, Yasukawa et al. [21] reported three cases of internal hernia associated with a colostomy after laparoscopic APR or HP. With the transperitoneal route, the small intestine can pass through the lateral defect, and an internal hernia may lead to a strangulated bowel obstruction. In contrast, there is no space between the lifted colon and the dissected lateral abdominal wall in the extraperitoneal route. Laparoscopic surgery is considered a potentially low-risk factor for adhesion [23]; however, with the transperitoneal route, the small intestine can pass through the lateral defect, and an internal hernia may result in strangulated bowel obstruction. An extraperitoneal route colostomy should be performed even when the laparoscopic approach has associated technical difficulties. In the present study, since transperitoneal route group had more bowel obstruction, we examined the details and found that transperitoneal route group included risk factors such as internal hernia and adhesion to the lifted colon. Three patients required surgical management due to an internal hernia associated with a colostomy, and five patients required surgical management due to adhesion to the lifted colon in the transperitoneal route group. However, there were no cases of internal hernia or adhesion to the tunneled colon in the extraperitoneal route group (Supplemental Table 2). In the transperitoneal route group, the colon is lifted through the abdominal free space. Here, the lifted colon may act like a band of bowel obstruction. Although there was a tendency to select a transperitoneal route in patients with higher BMI and longer operative time, there was no significant difference in the risk of bowel obstruction in these factors. Therefore, these factors were unlikely to be a risk for bowel obstruction. These findings suggest that the extraperitoneal route can prevent surgical correction of bowel obstruction due to an internal hernia or adhesion to the tunneled colon, which is needed for surgical management.

The strength of this study was its large sample size when comparing the development of PSH and bowel obstruction between the transperitoneal and extraperitoneal routes in a laparoscopic colostomy. However, several limitations should

Table 3 Univariate and multivariate analyses of risk factors for the development of a parastomal hernia

Variable	*Univariate analysis*		*Multivariate analysis*	
	Parastomal hernia/ total, n	*p*	*OR (95% CI)*	*p*
Age, year				
< 70	13/198 (6.6%)			
≥ 70	27/129 (20.9%)	0.0002	4.1 (2.0–8.6)	0.0002
Sex				
Male	29/194 (14.9%)			
Female	11/133 (8.3%)	0.09	1.5 (0.7–3.4)	0.32
BMI, kg/m^2				
< 22.4	11/158 (7.0%)			
≥ 22.4	29/169 (17.2%)	0.006	2.5 (1.1–5.5)	0.02
ASA score				
I	7/72 (9.7%)			
II	31/247 (12.6%)			
III	2/7 (28.6%)			
IV	0/1 (0%)	0.37		
History of abdominal surgical history				
No	23/228 (10.1%)			
Yes	17/99 (17.2%)	0.10		
Neoadjuvant therapy				
No	21/133 (15.8%)			
Yes	19/194 (9.8%)	0.12		
Approach				
Conventional laparoscopic surgery	38/308 (12.3%)			
Robot-assisted laparoscopic surgery	2/19 (10.5%)	1.00		
Procedure				
Abdominoperineal resection	29/261 (11.1%)			
Hartmann's procedure	11/66 (16.7%)	0.21		
Multivisceral resection				
No	38/308 (12.3%)			
Yes	2/19 (10.5%)	1.00		
Lateral lymph node dissection				
No	37/309 (12.0%)			
Yes	3/18 (16.7%)	0.47		
Stoma creation route				
Extraperitoneal	2/105 (1.9%)			
Transperitoneal	38/222 (17.1%)	0.00002	9.8 (2.3–42.3)	0.002
Operative time, min				
< 300	13/142 (9.2%)			
≥ 300	27/185 (14.6%)	0.71		
Blood loss, mL				
< 60	19/165 (11.5%)			
≥ 60	21/162 (13.0%)	0.74		

OR odds ratio, *CI* confidence interval, *BMI* body mass index, *ASA* American Society of Anesthesiologists

also be considered when interpreting our results. First, this was a retrospective study. Due to the retrospective design, the study was associated with some inherent limitations. In addition, the baseline characteristics were different between the two groups, especially the patients with higher BMI and longer operative time were more frequently in the transperitoneal route group than in the extraperitoneal route group. Therefore, a multivariate analysis had to be used to expose the

Table 4 Univariate and multivariate analyses of the risk factors for the development of bowel obstruction (Clavien–Dindo classification ≥ grade IIIa)

Variables	*Univariate analysis*		*Multivariate analysis*	
	Bowel obstruction/total, n	*p*	*OR (95% CI)*	*p*
Age, year				
< 70	12/193 (6.2%)			
≥ 70	17/134 (12.7%)	0.84		
Sex				
Male	18/194 (9.3%)			
Female	11/133 (8.3%)	0.84		
BMI, kg/m^2				
< 22.4	15/158 (9.5%)			
≥ 22.4	14/169 (8.3%)	0.70		
ASA score				
I	4/72 (5.6%)			
II	25/247 (10.1%)			
III	0/7 (0%)			
IV	0/1 (0%)	0.52		
History of abdominal surgical history				
No	16/228 (7.0%)			
Yes	13/99 (13.1%)	0.09	1.8 (0.8–4.0)	0.15
Neoadjuvant therapy				
No	12/133 (9.0%)			
Yes	17/194 (8.8%)	0.84		
Approach				
Conventional laparoscopic surgery	27/308 (8.8%)			
Robot-assisted laparoscopic surgery	2/19 (10.5%)	0.68		
Procedure				
Abdominoperineal resection	21/261 (8.0%)			
Hartmann's procedure	8/66 (12.1%)	0.33		
Multivisceral resection				
No	25/308 (8.1%)			
Yes	4/19 (21.0%)	0.08	3.0 (0.9–10.4)	0.08
Lateral lymph node dissection				
No	19/309 (6.1%)			
Yes	0/18 (0%)	0.39		
Stoma creation route				
Extraperitoneal	4/105 (3.8%)			
Transperitoneal	25/222 (11.3%)	0.04	3.3 (1.1–9.8)	0.03
Operative time, min				
< 300	12/142 (8.5%)			
≥ 300	17/185 (9.2%)	0.85		
Blood loss, mL				
< 60	13/165 (7.9%)			
≥ 60	16/162 (9.9%)	0.56		

OR odds ratio, *CI* confidence interval, *BMI* body mass index, *ASA* American Society of Anesthesiologists

potential risk factors for developing PSH and bowel obstruction. Second, the route used for stoma creation was different between individual surgeons and was based on the surgical situation. In the present study, we preferred the transperitoneal route in patients with a higher BMI and longer operation time because the transperitoneal route is advantageous in terms of its simplicity. However, choosing the extraperitoneal route can prevent the development of PSH and bowel obstruction.

Conclusions

This study showed that the transperitoneal route was a risk factor for developing both PSH and bowel obstruction after laparoscopic APR or HP. Our findings suggest that whenever possible, an extraperitoneal colostomy should be recommended, even with laparoscopic surgery. Further prospective multi-institutional randomized controlled studies between the transperitoneal and extraperitoneal routes are needed to identify the therapeutic benefits of the extraperitoneal route with laparoscopic surgery.

Supplementary information The online version contains supplementary material available at https://doi.org/10.1007/s00384-022-04187-7.

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Author contribution Emi Ota, Tomohiro Yamaguchi, and Yosuke Fukunaga contributed to the conception and design of the study, acquisition, analysis, and interpretation of the data, and drafting and critically revising the manuscript for important intellectual content. Toshiya Nagasaki, Hironori Fukuoka, Toshiki Mukai, Yukiharu Hiyoshi, Tsuyoshi Konishi, and Takashi Akiyoshi contributed to the acquisition of data and critical revision of the manuscript for important intellectual content. All authors have read and approved the final manuscript.

Declarations

Ethical approval This research study was conducted retrospectively from data obtained for clinical purposes. We consulted extensively with the IRB of the Cancer Institute Hospital who approved the study (protocol no.2018–1109).

Competing interests The authors declare no competing interests.

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