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Risk Factors for Complications After Laparoscopic Surgery in Colorectal Cancer Patients: Experience of 401 Cases at a Single Institution

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Abstract

Background Laparoscopic surgery is widely used for the treatment of colorectal cancer, but little is known about perioperative risk factors for complications.

Methods Clinical data were reviewed for 401 consecutive unselected colorectal cancer patients who underwent laparoscopic surgery at Kyoto Medical Center between 1998 and 2005. The outcome variable was incidence of postoperative complications. Using logistic regression analysis, 58 background, clinical, preoperative, and intraoperative factors were assessed as potential predictors of complications.

Results The set of independent protective factors that had the greatest influence on the incidence of local complications after colon surgery was as follows: cefmetazole use for prophylaxis (versus oral only; adjusted odds ratio (OR) 0.18, 95% confidence interval (CI) 0.06–0.54), high operative infusion rate (per ml/min; OR 0.82, 95% CI 0.70–0.95), regular laxative use (OR 0.33, 95% CI 0.12–0.79), and double-stapled anastomosis (versus hand-sewn; OR 0.15, 95% CI 0.03–0.83). Independent risk factors for local complications after rectal surgery were abdominoperineal resection (versus low anterior resection, OR 4.84, 95% CI 1.64–14.9), long operative time (per hour, OR 1.55, 95% CI 1.11–2.23), and history of heart disease (OR 5.18, 95% CI 1.34–21.5). The occurrence of complications was not found to be associated with overall survival in this study.

Conclusions We identified intraoperative management such as low operative infusion rate is one of the independent significant risk factors for complications after laparoscopic surgery for colorectal cancer in addition to patient characteristics and surgical procedure.

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Introduction

Colorectal cancer, a leading cause of death in developed countries, remains a major medical challenge. When colorectal surgery is performed, it is important to reduce the complication rate so as to improve patients' quality of life, and to minimize the length of the hospital stay and the cost of medical care. Laparoscopic surgery for colorectal cancer was first reported in 1991 [1], and over the ensuing years, it has become increasingly popular, and now tends to be favored over open surgery. The advantages of laparoscopic surgery over open surgery are well established; laparoscopic surgery is associated with less pain, a more rapid recovery of bowel function, and a shorter hospital stay. Moreover, no significant differences have been found in the oncologic outcomes of laparoscopic surgery and

open surgery for colorectal cancers [2–5]. However, although laparoscopic colorectal surgery is less invasive, postoperative complications still occur at a steady rate, and the predictive factors for complications are poorly understood [6–11]. In particular, there have been few studies that identify risk factors after colon and rectal surgery separately, though there are large differences between colon and rectal surgery, with types of complications differing greatly according to procedure.

In the present study we focused on identifying the predictors of complications in colon and rectal cancer patients who underwent laparoscopic surgery in a single institution.

Methods

Patients and procedures

After obtaining approval from the institutional ethics committees of Kyoto Medical Center and Kyoto University, we retrospectively collected clinical data for Japanese patients who had undergone laparoscopic surgery for colorectal cancer at the Department of Surgery, Kyoto Medical Center, between January 1998 and June 2005. Because Kyoto Medical Center is an educational institution, 14 different surgeons (including senior residents) had performed the laparoscopic operations under the supervision of two senior colorectal surgeons (H. Kuroyanagi and Y. Sakai).

More than 97% of the patients studied underwent standard mechanical bowel preparation, regardless of whether the patient had been using laxatives regularly. As chemical preparation, oral antibiotics were administered the day before operation, and prophylactic systemic antibiotics were administered just before or during the procedure. All patients received oral and/or systemic antibiotics.

For the operation the patient was in a modified lithotomy position, and the five-port method described by Weiser and Milsom [12] was employed via the medial approach with low-pressure (8 mmHg) CO_2 pneumoperitoneum. Anastomotic type with staples or hand sutures was decided on a case-by-case basis. Conversion to open surgery was permitted when necessary for patient safety.

Patients with pathological stage I–IV disease were followed up according to the standard surveillance schedule. Postoperative 5-fluorouracil-based chemotherapy was administered to 72.9% of stage III and IV disease, and only one patient with stage III disease underwent postoperative radiotherapy.

Outcome of interest

The study endpoints were incidence of complications and overall survival. Complications were defined as any adverse effects of grades 2–5 (NCI-CTCAE version 3.0). Grade 1 adverse effects such as skin redness or ileus without symptoms were excluded because they were not considered clinically important. Postoperative complications were defined as those that occurred within 30 days of the operation. Local complications were defined as those that occurred in the abdominal cavity or at the surgical site, and all other complications were deemed to be systemic complications. Overall survival (OS) was defined as the time between the operation and death from any cause.

Potential predictors

As potential predictive factors, we used background, preoperative, and intraoperative factors (Tables 1 and 2). Ten co-morbidities and five drugs of regular use were analyzed separately. Hematological data were analyzed as continuous variables. Because of the skewed nature of the carcinoembryonic antigen (CEA), carbohydrate antigen (CA) 19-9, C-reactive protein (CRP), and lactase dehydrogenase (LDH) distributions, natural logarithms of those values were used. The intraoperative fluid infusion rate (ml/min) was defined as the total volume of fluid infused during the operation divided by the operative time.

Statistical analysis

Univariate analysis and multiple logistic regression analysis with stepwise selection were performed to identify the factors that had significant independent effects on complication rate, while adjusting for the effects of other factors included in the model. A p value of 0.05 was used for variable selection in univariate analysis, and was regarded as statistically significant in multivariate analysis. The OS curves were estimated using the Kaplan-Meier method, and the log rank test was used to assess differences between the curves. In the analysis of local complications of the colon and rectum, patients who underwent total colectomy or Hartmann's procedure were excluded, because the procedures are much different from others and there were few cases of them in this study. All statistical analysis was performed using SAS version 9.1 (SAS Institute, Cary, NC).

Results

A total of 498 laparoscopic colorectal procedures were performed at Kyoto Medical Center during the study period. Of these, 401 involved resection of adenocarcinoma of the colon ($n = 279$) or rectum ($n = 122$). The remaining

Table 1 Clinical characteristics of patients with colon and rectal cancer

		Colon cancer ($n = 279$)	Rectal cancer ($n = 122$)
Year of operation	98–02/03–05	115 (41)/164 (59)	35 (29)/87 (71)
Gender	Male/female	150 (54) / 129 (46)	71 (58)/51 (42)
Age (years)[a]		67 (8–94)	65 (26–88)
BMI (kg/m^2)[b]		22.2 ± 3.2	22.2 ± 3.1
Smoking	(–)/(+)/cessation	195/55/23	69/38/11
Alcohol	(–)/(+)/cessation	142/119/3	47/69/1
ASA-PS	1/2/3	119/136/23	52/59/11
No. of previous laparotomies	0/1/≥2	172/92/13	74/40/7
Bowel obstruction		18 (6)	10 (8)
Heart disease		28 (10)	14 (11)
Other 8 co-morbidities		185 (66)	78 (64)
Regular use of laxative		94 (34)	51 (42)
Regular use of other 4 drugs		58 (21)	17 (14)
Preoperative CV		13 (5)	13 (11)
Preoperative blood transfusion		9 (3)	2 (2)
Preoperative CRT		4 (1)	25 (20)
EMR		34 (12)	3 (2)
Ascites		6 (2)	7 (6)
Hematological data			
WBC ($\times 10^9$/l)[b]		6.0 ± 1.7	6.3 ± 2.1
Hb (g/dl)[b]		12.4 ± 2.2	12.8 ± 2.0
ALB (g/dl)[b]		4.1 ± 0.5	4.0 ± 0.5
LDH (IU/l)[a]		212 (101–1295)	189 (115–1,083)
CRP (mg/dl)[a]		0.12 (0.01–14.6)	0.09 (0.01–14.7)
CEA (ng/ml)[a]		3.2 (<0.5–34,415.6)	4.1 (0.7–953.9)
Differentiation	High/Mod./Other	141/127/11	49/68/5
Tumor size (mm)[b]		40 ± 22	47 ± 20
Clinical T stage	T1/T2/T3/T4	75/60/91/49	20/19/50/31
Clinical N stage	N0/N(+)	227 (84)/42 (16)	82 (68)/39 (32)
Clinical M stage	M0 / M1	26 (98)/6 (2)	117 (96)/5 (4)
Clinical stage[c]	0/I/II/III/IV	25/88/75/69/22	6/28/35/36/17

Values in parentheses are percentages unless indicated otherwise

[a] Values are expressed as median (range)

[b] Values are expressed as mean ± standard deviation

[c] Value was not used for analysis because it was calculated from TNM staging data. Other 8 comorbidities are hypertension, stroke, diabetes, respiratory disease, mental illness, renal disease, liver disease, and anemia. Other 4 drugs are cimetidine, non-steroidal anti-inflammatory drugs, steroid, and statin

BMI body mass index; *ASA-PS* American Society of Anesthesiologists Physical Status; *CV* central venous access; *CRT* chemo-radio therapy; *EMR* endoscopic mucosal resection; *WBC* white blood cell count; *ALB* serum albumin level; *LDH* serum LDH level; *CRP* serum CRP level; *CEA* carcinoembryonic antigen

97 patients were excluded because they did not have malignant disease. A total of 98.4% (364/370) of the patients with stage I–IV disease were followed up as scheduled until December 2006. The median follow-up time for all patients was 35 months (range: 1–101 months).

No patients required emergency surgical treatment during the study period (all surgical procedures performed during this time were elective). The preoperative values of various parameters are shown in Table 1, and surgical data are shown in Table 2. Extent of node dissection was categorized by the Japanese Classification [13]. There was no postoperative mortality (i.e., mortality within 30 days of the operation), and the rate of intraoperative complications was 0.2% (one patient recovered from cardiac arrest;

Table 2 Perioperative data

	Colon cancer ($n = 279$)	Rectal cancer ($n = 122$)
Oral antibiotics	236 (85)	109 (89)
Type of prophylaxis		
oral only/CMZ/other	22/198/59	10/102/10
Timing of prophylaxis administration		
preoperative/intraoperative	233 (84)/24 (9)	109 (89)/3 (2)
Surgical procedure		
Rt/Lt/Sig/Part/Total	86/33/143/14/3	–
LAR/APR/Hart	–	97/23/2
Surgeon		
A/B/C/other	84/91/45/59	29/43/31/19
Operative time (min)[a]	218 (81–668)	303.5 (156–653)
Blood loss (g)[a]	25 (5–1570)	75 (10–820)
Fluid infusion rate (ml/min)[a]	8.9 (1.7–19.9)	8.9 (3.6–18.9)
Urine volume (ml)[a]	260 (40–2500)	415 (30–1530)
Additional resection	41 (15)	22 (18)
Blood transfusion	5 (2)	3 (2)
Drain	80 (29)	52 (43)
Conversion to open surgery	8 (3)	5 (4)
Type of anastomosis		
none/hand-sewn/FETE/DST	1/9/133/136	25/7/0/90
Stoma	2 (1)	41 (34)
Extent of node dissection[b]		
D0/D1/D2/D3	1/20/98/160	0/66/27/29
Residual tumor		
R0/R1/R2/RX	257/3/17/2	102/5/15/0

Values in parentheses are percentages unless indicated otherwise

[a] Values are median (range)

[b] Categorized according to the Japanese criteria [13]

Rt right-sided colectomy; *Lt* left hemicolectomy; *Sig* sigmoid colectomy and high anterior resection; *Part* partial colectomy; *Total* total abdominal colectomy and total proctocolectomy; *LAR* low anterior resection; *APR* abdominoperineal resection; *Hart* Hartmann's procedure; *CMZ* cefmetazole; *FETE* functional end-to-end anastomosis; *DST* double-stapled technique, including anastomoses by circular staplers

Table 3 Type and grade of complications

	Colon cancer ($n = 279$)			Rectal cancer ($n = 122$)		
	Grade (CTCAE version 3.0)					
	2	3	4	2	3	4
Surgical site infection	24	1	0	10	2	0
Ileus or bowel complications	11	2	0	11	0	1
Anastomotic complications	2	2	0	6	1	0
Wound dehiscence	3	0	0	1	1	0
Urinary dysfunction	0	0	0	2	2	0
Heart complications[a]	2	0	0	0	0	1
Lung complications	3	0	0	0	0	0
Acute stroke	0	1	0	1	0	0
Other complications	2	1	0	6	0	0
Total	47	7	0	37	6	2

[a] Includes one intraoperative cardiac arrest

CTCAE Common Terminology Criteria for Adverse Events

1/401). The incidence of postoperative complications was 22.2% (colon, 48/279; rectum, 41/122). The types of complications observed are shown in Table 3. No significant difference in complication rate was found based on the experience of surgeon.

Predictors of Local Complications for Colon Surgery

Local complications were observed in 41 patients with colon cancer. A total of 13 factors that were potential predictors of local complications of colon surgery were

Table 4 Analysis of risk factors for local complications of colon surgery (41 events/276 patients)

Variable	Category	Univariate analysis			Multivariate analysis		
		OR	95% CI	*p* Value*	OR	95% CI	*p* Value*
Type of prophylaxis	CMZ vs oral only	0.18	0.07–0.48	< 0.001	0.18	0.06–0.54	0.006
	others vs oral only	0.60	0.21–1.70		0.32	0.09–1.07	
Intraoperative infusion rate	per ml/min	0.80	0.70–0.92	0.001	0.82	0.70–0.95	0.011
Type of anastomosis	FETE vs hand sewn	0.25	0.06–1.05	0.002	0.40	0.08–2.04	0.019
	DST vs hand sewn	0.09	0.02–0.40		0.15	0.03–0.83	
Regular laxative use	(+) vs (–)	0.29	0.12–0.72	0.007	0.33	0.12–0.79	0.021
Timing of prophylaxis	Pre-op vs none	0.22	0.09–0.58	0.002			
	Intra-op vsnone	0.72	0.21–2.48				
Type of oral antibiotics	KM + MET vs None	0.25	0.11–0.59	0.003			
	others vs none	0.71	0.29–1.73				
Drain	(+) vs (–)	2.62	1.33–5.18	0.006			
Tumor differentiation	Others vs high	0.37	0.18–0.76	0.007			
Surgical procedure	Sigmoidectomy vs. others	0.42	0.21–0.85	0.016			
Year of operation	2,001 vs 98–2,000	1.13	0.36–3.51	0.017			
	2,002 vs 98–2,000	0.81	0.26–2.58				
	2,003 vs 98–2,000	0.23	0.06–0.84				
	2,004 vs 98–2,000	0.40	0.11–1.41				
	2,005 vs 98–2,000	0.16	0.03–0.86				
Clinical T stage	T2 vs T1 + Tis	0.32	0.12–0.85	0.025			
	T3 vs T1 + Tis	0.32	0.13–0.74				
	T4 vs T1 + Tis	0.49	0.19–1.26				
Extent of node resection[a]	D2 vs D1 + D0	0.39	0.14–1.12	0.036			
	D3 vs D1 + D0	0.26	0.09–0.73				
Gender	Female vs male	0.49	0.24–0.99	0.049			

* *p* Value for global association from logistic regression analysis

[a] Categorized by the Japanese classification [13]

Variables selected by univariate analyses ($p < 0.05$) were entered into a multivariate logistic regression model with stepwise selection

OR odds ratio; *CI* confidence interval; *CMZ* cefmetazole; *FETE* functional end-to-end; *DST* double-stapled technique; *KM* kanamycin; *MET* metronidazole

identified in the univariate analysis. Factors that were found by multivariate analysis to significantly and independently predict a lower rate of local complications were these: type of prophylaxis (CMZ), higher intraoperative infusion rate, regular laxative use and type of anastomosis (double stapled). Year of operation showed learning curve in univariate analysis, but it was not selected in the multivariate analysis (Table 4).

Predictors of local complications for rectal surgery

Local complications were observed in 35 patients with rectal cancer. Eight factors were identified as predictors of local complications of rectal surgery by univariate analysis. Factors that were found by multivariate analysis to significantly and independently predict a lower rate of local complications were these: shorter operative time, surgical procedure (low anterior resection), and absence of a history of heart disease (Table 5).

Predictors of systemic complications

Fifteen of the 401 colorectal cancer patients developed systemic complications. Two factors that were predictors of systemic complications were identified with the univariate analysis: preoperative central venous access (odds ratio (OR) 6.00, 95% confidence interval (CI) 1.77–20.4, $p = 0.004$) and preoperative serum albumin level (g/dl, OR 0.25, 95% CI, 0.10–0.60, $p = 0.002$). Multivariate analysis with these factors showed that only preoperative serum albumin level was associated with the rate of systemic complications.

Table 5 Analysis of risk factors for local complications of rectal surgery (35 events/120 patients)

Variable	Category	Univariate analysis			Multivariate analysis		
		OR	95% CI	*p* Value*	OR	95% CI	*p* Value*
Surgical procedure	APR vs LAR	7.22	2.69–19.4	<0.001	4.84	1.64–14.9	0.005
Operative time	per hour	1.81	1.31–2.50	<0.001	1.55	1.11–2.23	0.014
History of heart disease	(+) vs (–)	4.74	1.43–15.7	0.01	5.18	1.34–21.5	0.018
Stoma	(+) vs (–)	3.86	1.68–8.88	0.002			
Blood loss	200–400 vs < 200	3.00	1.09–8.28	0.002			
	> 400 vs < 200	7.20	2.14–24.3				
Clinical N stage	N(+) vs N0	3.05	1.32–7.01	0.009			
Additional resection	(+) vs (–)	3.08	1.19–8.00	0.021			
Gender	Female vs male	0.37	0.16–0.89	0.026			

* *p* Value from logistic regression analysis

Variables selected by univariate analyses ($p < 0.05$) were entered into a multivariate logistic regression model with stepwise selection

OR odds ratio; *CI* confidence interval; *APR* abdominoperineal resection; *LAR* low anterior resection

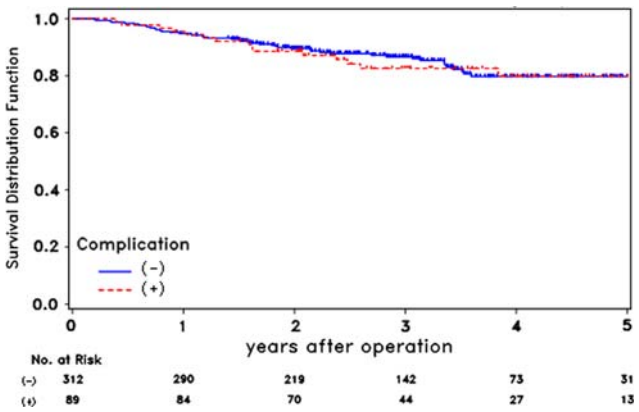

Fig. 1 Overall survival curves for patients with or without complications

Overall survival

There was no significant difference in OS between the rectal cancer group and the colon cancer group ($p = 0.694$ after adjustment by stage) (Fig. 1). The 3-year OS for all patients was 85.7% (95% CI, 82.0–89.4; colon, 87.5%; rectum, 81.6%). The occurrence of complications was not related to overall survival ($p = 0.826$) (Fig. 1).

Discussion

The results of several major clinical trials have shown that the oncologic outcome after laparoscopic surgery is comparable to that after open surgery [2–5]. Kirchhoff et al. [11] found that of 20 general background factors analyzed, the following 5 were significant factors for complications following laparoscopic colorectal procedures as an initial report: surgeon's level of experience, patient age, patient gender, American Society of Anesthesiologists Physical Status (ASA-PS) class, and neoplasia. In the present study, although some of these factors were identified as significant by univariate analysis, none of them were found to be significant in multivariate analysis. A possible reason for this is that perioperative factors may be more important than background factors for predicting complications after laparoscopic surgery in patients with colorectal cancer.

In the present study, which only included patients with malignant disease who underwent laparoscopic surgery at a single institution, the quality of the surgical procedures was consistently high, and the data were sufficiently reliable. Although 14 different surgeons performed the laparoscopic procedures, median blood loss (colon cancer: 25 g; rectal cancer: 75 g) was markedly less, the conversion rate to open surgery (3.2%) was very much lower, and the survival rate in patients with disease of each stage was substantially higher than corresponding values reported in previous studies [2–4]. Furthermore, the 30-day mortality rate was zero, and the operative complication rate was acceptable (89/401). For each clinical factor, data were missing in an average of only 0.8% of cases.

The U. S. Centers for Disease Control and Prevention guidelines recommend antimicrobial prophylaxis for gram-negative bacilli and anaerobes before and during colorectal operations [14], and cephamycins are recommended in Europe [15] and by the U. S. National Surgical Infection Prevention Project [16]. Our results support these recommendations: the complication rate was lower in the cephamycin (cefmetazole) group than in the "other drug" group and the "oral only" group.

We found that the intraoperative infusion rate was a significant independent predictor of early local complications after colon surgery, with a higher intraoperative infusion rate being associated with a lower incidence of

local complications (<400 ml/h, 28.6%; 400–500 ml/h, 16.4%; 500–600 ml/h, 13.1%; > 600 ml/h, 7.1%). In a PubMed literature search, we were able to find only a few articles concerning postoperative complications and infusion rate [17, 18], and the present study is the first in which low infusion rate during laparoscopic colorectal cancer surgery has been identified as a risk factor for complications. We recommend an intraoperative infusion rate of more than 500 ml/h during laparoscopic colon cancer surgery. In support of this recommendation, Holte et al. found that morbidity tended to increase with a "restrictive" fluid regimen in fast-track colonic surgery [19], and that administration of greater amounts of fluid intraoperatively improved postoperative outcome after laparoscopic cholecystectomy [17]. In contrast, Brandstrup et al. [18] found that a restricted perioperative intravenous fluid regimen (with the aim of maintaining body weight) reduced complications after elective colorectal resection. Because the nature of the surgical procedures employed in that study is unclear, the relevance of the results is doubtful for patients undergoing laparoscopic surgery. More intraoperative fluid infusion may be required for laparoscopic procedures than for open surgeries.

Our finding that the type of anastomosis was a significant independent predictor of early local complications after colon surgery is supported by a Cochrane review that notes that stapled functional end-to-end (FETE) ileocolic anastomoses are associated with fewer leaks than hand-sewn anastomosis [20]. In the present study, we found that stapled FETE anastomoses were associated with fewer local complications than hand-sewn anastomoses, and that the double-stapled technique was associated with considerably fewer local complications than hand-sewn anastomoses.

Epidemiological studies have produced conflicting results with regard to whether regular use of laxatives increases the risk of colon cancer [21, 22], but to the best of our knowledge the relationship between laxative use and complications has never been studied. In our study, the regular use of laxatives was found to reduce postoperative morbidity. We administered preoperative laxatives to most patients as standard bowel preparation for surgery. However, recent studies have shown that preoperative laxative use may increase postoperative complications [23]. We speculate that using laxatives regularly rather than preoperatively may be more desirable, in that the adverse effects associated with preoperative use may be avoided.

In rectal surgery, the operative time and surgical procedure are well established as factors contributing to the rate of postoperative complication, which the results of the present study support. In the present study we found that a history of heart disease was related to a higher incidence of local complications after laparoscopic rectal surgery especially about infectious complications. The relationships between obesity and heart disease, and between obesity and surgical site infection have been often discussed in the literature [24], but the relationship between heart disease and surgical site infection has rarely been explored. Among rectal cancer patients, heart disease may increase susceptibility to infection.

Although the presence of postoperative complications has been previously found to be an independent predictor of overall survival [25], this was not the case in the present study. The reason for this difference may be the low incidence of severe complications in the present study (no postoperative deaths), and appropriate management of postoperative complications may have led to favorable outcomes.

This study was an exploratory analysis, and selection bias might influence the results. Thus the factors identified in this study require confirmation in future research. Nevertheless, despite the preliminary nature of the present results, they are still important because there have been few prior studies involving exhaustive analysis of factors related to the incidence of complications after laparoscopic colorectal cancer surgery.

Conclusions

We identified several factors that are independent and significant predictors of complication rate after laparoscopic colorectal cancer surgery. Perioperative factors were found to be more important than background factors in reducing the incidence of complications. When performing laparoscopic surgery for colorectal cancer, surgeons should give consideration to perioperative conditions such as prophylaxis and fluid administration, as well as to patient characteristics and the surgical procedure.

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