

A novel difficulty scoring system for
laparoscopic colorectal cancer surgery
for appropriate case selection according to master

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Abstract

Mastering laparoscopic colorectal cancer surgery involves a learning curve. Inexperienced surgeons require appropriate case selection. Nonetheless, there are few indicators for predicting the difficulty of laparoscopic colorectal cancer surgery. We established a difficulty scoring system to facilitate appropriate case selection during the learning curve for laparoscopic colorectal cancer surgery until mastery is achieved.

We reviewed 1,390 laparoscopic colorectal cancer surgery cases performed at our hospital. Surgical duration was used as an index of surgical difficulty. Factors related to surgical difficulty were identified using a multivariate analysis and were scored using a linear regression analysis.

Overall, 889 patients were included in the analysis. Sex, body mass index $> 25 \text{ kg/m}^2$, and tumor location were factors that best defined surgical difficulty. The difficulty was determined by the sum of prolonged surgical duration predicted by these three factors. Surgical duration and hospital stay were longer, blood loss was greater, and complications were more common in the high difficulty group than in the low and medium difficulty groups. The developed scoring system showed high reliability in ten-fold cross-validation.

The scoring model we developed can predict surgical difficulty for typical laparoscopic colorectal cancer surgery and may be useful in selecting appropriate surgical cases for inexperienced surgeons.

Key words : laparoscopic colorectal surgery, colorectal cancer, learning curve, cross validation, scoring system

I. Introduction

Colorectal cancer is the third most common cancer diagnosed worldwide, with approximately

1,800,000 new cases and approximately 881,000 deaths in 2018¹⁾. Long-term results of laparoscopic colorectal cancer surgery (LCCS) have not been reported to be inferior to those obtained in open surgery²⁻⁶⁾. The American Society of Colon and Rectal Surgeons describes

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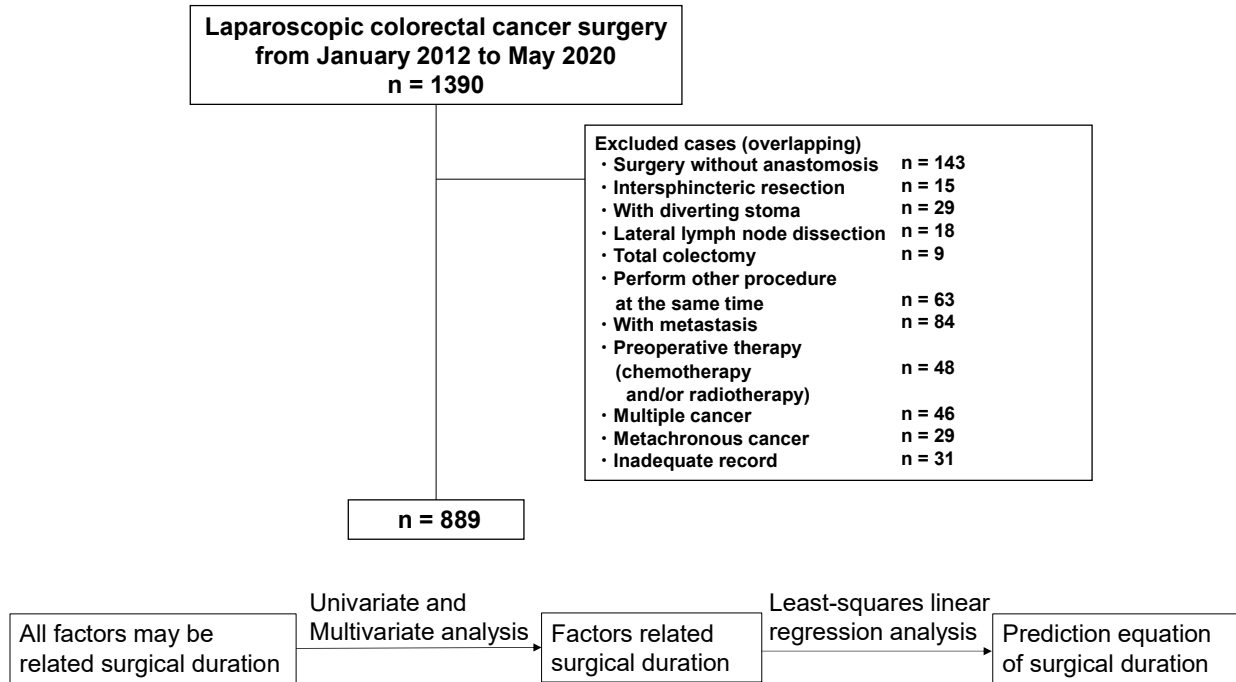


Fig. 1. The study flow chart depicting the exclusion criteria and study methods for this study.

LCCS as a minimally invasive approach^{7, 8)}, and laparoscopic surgery has become a widely used method for colorectal cancer treatment in Japan⁹⁾. However, this procedure should be performed by experienced surgeons to ensure that the short-term and long-term results are equivalent to those of open surgery⁷⁻⁹⁾. In particular, transverse and descending colon cancers are excluded from open versus laparoscopic trials due to their anatomical complexity, and laparoscopic surgery should be carefully considered in particular circumstances, such as with T4 colon cancer, larger-sized tumors, locally advanced cancer, and comorbidities with obesity^{2-4, 10-14)}. Although it is very difficult to evaluate the skills of each surgeon and those available at each institution, differences in the outcomes of LCCS between institutions have been reported^{12, 15)}.

Some experience is required to learn LCCS^{3, 16)}. Nonetheless, there has been no

report on an objective index of the types of cases that are suitable for inexperienced surgeons while learning to master the technique. Therefore, the present study aimed to construct a scoring system to predict the surgical difficulty of LCCS and to facilitate appropriate case selection according to the surgeon's proficiency.

II. Materials and Methods

1. Patients

We retrospectively analyzed cases of LCCS performed at our hospital. The study protocol was approved by the Research Ethics Committee of Iwate Medical University School of Medicine (MH2019-121). Informed consent for laparoscopic surgery was obtained from all patients. A total of 1,390 cases of LCCS performed on a standby basis at our hospital between January 2012 and May 2020 were included in this study. The exclusion

criteria for this study were surgery without anastomosis (Hartmann's surgery and abdominoperineal resection), intersphincteric resection, surgery with a diverting stoma, lateral lymph node dissection, total colectomy, simultaneous performance of other procedures, with metastasis, preoperative therapy (chemotherapy and/or radiotherapy), multiple cancers, metachronous cancers, and incomplete medical records (Fig. 1). Tumor location was confirmed by barium enema or computed tomography colonography in all cases.

2. Study design

During the study period (2012–2020), there were two qualified surgeons at our institution, based on using the endoscopic surgical skill qualification system in Japan¹⁷⁾ in the field of colorectal surgery, and they participated as surgeons or assistants in all cases included in this study. In this study, the surgical difficulty index was defined as the surgical duration. Factors affecting surgical duration were analyzed, including age, sex, body mass index (BMI), American Society of Anesthesiologists Physical Status (ASA-PS), tumor location, previous open surgery, T category, N category, tumor stage, and surgeries performed by an endoscopic surgical skill qualification system-qualified surgeon. Ordinal and nominal variables were analyzed as is. Cutoff values were defined for the continuous variables of age and BMI. The cutoff value for age was 65 years old, which is defined as elderly by the World Health Organization, and the cutoff value for BMI was 25, which is defined as obese by the Japan Society for the Study of Obesity.

First, factors related to surgical duration were analyzed univariately, and a multivariate

analysis was performed on the extracted factors. Second, predictive equations for surgical duration were developed using a least-squares linear regression model for the factors extracted in the multivariate analysis. Third, the prolongation time was calculated from this prediction equation, and surgical difficulty was accordingly divided into the following three groups according to the total prolongation time: low, medium, and high difficulty. Fourth, surgical duration, blood loss, conversion to open surgery, complications, and length of postoperative hospital stay were evaluated among the three difficulty groups. Postoperative complications were evaluated according to the Clavien-Dindo classification¹⁸⁾. Finally, 10-fold cross-validation was performed to assess this scoring system.

3. Surgical procedure

General anesthesia and pneumoperitoneum were administered to all patients. Abdominal air pressure was set at 8–10 mmHg. In all cases, the lithotomy position was used during surgery. The surgeon, assistant surgeon, and scopist performed the operation using five ports. A medial approach with central lymph node dissection was used first in any surgical design. Any surgeon performed the surgery, which was standardized in our facility¹⁹⁾. Functional end-to-end anastomosis or a double-stapling technique was used for intestinal anastomosis, depending on tumor location. All functional end-to-end anastomoses were performed extracorporeally.

We performed D3 dissection for colorectal cancer based on the Japanese guidelines⁹⁾. Both proximal and distal margins were 10 cm beyond the tumor, and complete dissection was performed for all regional lymph nodes. In

Table 1. Patients and tumor characteristics

Variables
Age (year), median (range)
Sex (male), n (%)
BMI (kg/m ²), median (range)
ASA-PS (1, 2, 3, 4), n (%)
Previous open surgery, n (%)
Tumor location (C, A, T, D, S, RS, Ra, Rb), n (%)
T category (Tis, T1, T2, T3, T4a, T4b), n(%)
N category (N0, N1a, N1b, N2a, N2b, N3), n (%)
Stage (0, I, II a, II b, II c, III a, III b, III c), n (%)
Percentage of surgeries performed by endoscopic surgical skill qualified surgeon (C, A, T, D, S, RS, Ra, Rb, all procedure), n (%)

BMI, Body mass index; ASA-PS, American Society of Anesthesiologists Physical Status; C, cecum; A, ascending colon; T, transverse colon; D, descending colon; S, sigmoid colon; RS, rectosigmoid colon; Ra, rectum above the peritoneal reflection; Rb, rectum below the peritoneal reflection.

ileocecal resection, the ileocecal vessels were divided, and the lymph nodes were dissected. In addition to this, the right colonic artery and the right branch of the middle colonic artery were divided, and the lymph nodes were dissected in right hemicolectomy. For partial resection of the transverse colon, the lymph nodes at the root of the middle colonic artery were dissected, and the root or only the right or left branch of the middle colonic artery was divided, depending on tumor location. In left hemicolectomy, the left colonic artery and the left branch of the middle colonic artery were divided. The lymph nodes at the root of the inferior mesenteric artery were also dissected; however, the inferior mesenteric artery itself was preserved. In sigmoidectomy and rectal resection, the inferior mesenteric artery was divided at its root, or the left colonic artery was preserved and divided on the peripheral side after dissecting the lymph nodes at the root. In Japan, this type of surgery is commonly performed as D3 lymph node

dissection²⁰⁻²².

4. Statistical analysis

Categorical variables are expressed as total numbers and percentages, whereas continuous data are presented as median values. The chi-square test was employed for categorical data, whereas the Kruskal–Wallis test or Steel–Dwass test was used for continuous data. Multivariate analysis was performed on factors extracted by univariate analysis. Statistical significance was considered as p -values < 0.05 . A least-squares linear regression model was used to determine factors affecting the surgical duration for the assessment of surgical difficulty. All statistical analyses were performed using JMP software version 16.0.0 (SAS Institute, Inc., Cary, NC, USA).

III. Results

1. Patient background and surgical outcomes

Out of 1,390 patients, 501 were excluded, leaving 889 patients for analysis. The

 n = 889

68 (24–94)
 456 (51.3)
 23.1 (12.5–56.3)
 164 (18.4), 617 (69.4), 106 (11.9), 2 (0.2)
 141 (15.9)
 98 (11.0), 125 (14.1), 92 (10.3), 49 (5.5), 226 (25.4), 111 (12.5), 103 (11.6), 85 (9.6)
 9 (1.0), 181 (20.4), 155 (17.4), 490 (55.1), 48 (5.4), 6 (0.7)
 555 (62.4), 125 (14.1), 108 (12.1), 68 (7.6), 33 (3.7), 0 (0.0)
 8 (0.9), 280 (31.5), 254 (28.6), 10 (1.1), 3 (0.3), 51 (5.7), 241 (27.1), 42 (4.7)
 45 (45.9), 71 (56.8), 81 (88.0), 38 (77.6), 81 (35.8), 83 (74.8), 96 (93.2), 82 (96.5), 577 (64.9)

background and surgical results of the analyzed cases are shown in Tables 1 and 2, respectively. The surgical technique was selected according to the Japanese classification of colorectal cancer, based on tumor location²³). There were 171 ileocecal resections, 91 right hemicolectomies, 56 partial resections of the transverse colon, 49 left hemicolectomies, 223 sigmoidectomies, 112 high anterior resections, and 187 low anterior resections. The percentage of surgeries performed by surgeons qualified by the endoscopic surgical skill qualification system was relatively high for the transverse colon, descending colon, and lower rectum procedures. The median surgical duration for all operations was 187 minutes (interquartile range [IQR] 160–218 minutes), and the median blood loss was 10 mL (IQR 5–18 mL). In seven patients (0.8%), the procedure was converted to open surgery. The median length of postoperative hospital stay was 8 days (IQR 7–10 days). Complications with Clavien–Dindo

classification ≥ 3 occurred in 30 patients (3.4%). No operative mortality was observed.

2. Factors determining surgical difficulty and scoring model for LCCS

Univariate analysis showed that male sex, BMI ≥ 25 kg/m², and tumor location were associated with prolonged surgical duration. In the multivariate analysis, these associations remained significant (Table 3). Using these three factors, a prediction equation for surgical duration was obtained by least-squares linear regression analysis (Fig. 2). The degree of prolongation associated with each of these factors obtained using this prediction equation was used as a score (Table 4). For example, $11.6 + 12.0 + 24.7 = 48.3$ for males, BMI ≥ 25 kg/m², and tumor location in the transverse colon and $0 + 0 + 10.3 = 10.3$ for females, BMI < 25 kg/m², and tumor location in the sigmoid colon. The total score was used to determine the difficulty of the case. Surgical difficulty was classified into three levels: low difficulty, score ≤ 20 ; medium

Table 2. Operative outcomes of the laparoscopic colorectal cancer surgery

Operative procedure	Ileocecal resection	Right hemicolectomy	Partial resection of the transverse colon
Number of patients	171	91	56
Surgical duration (minutes), median (IQR)	170 (145–199)	192 (165–222)	191(154–214)
Blood loss (mL), median (IQR)	12 (7–21)	14 (7–24)	10 (7–30)
Conversion to open surgery, n (%)	2 (1.2)	3 (3.3)	0 (0.0)
Postoperative hospital stay (day), median (IQR)	8 (7–11)	8 (7–10)	9 (7–10)
Morbidity Clavien–Dindo grade \geq 3, n (%)	4 (2.3)	2 (2.2)	1 (1.8)
Mortality, n (%)	0 (0.0)	0 (0.0)	0 (0.0)

IQR, interquartile range

Table 3. Correlations between surgical duration and clinical factors

Independent variables	Univariate analysis p value*	Multivariate analysis p value**
Age \geq 65 years	0.0586	
Sex	< 0.0001	< 0.0001
BMI \geq 25 kg/m ²	< 0.0001	< 0.0001
ASA-PS	0.1686	
Tumor location	< 0.0001	< 0.0001
Previous open surgery	0.9065	
T category	0.2086	
N category	0.2499	
Stage	0.4907	
Surgeries performed by endoscopic surgical skill qualified surgeon	0.1708	

* Wilcoxon signed rank test

** Multiple regression analysis, least squares method

BMI, body mass index; ASA-PS, American Society of Anesthesiologists Physical Status.

difficulty, score 20–40; and high difficulty > 40.

3. Evaluation by the scoring model

Median (IQR) surgical duration (minutes) was significantly different for each difficulty level: low vs. medium (170 [147–197] vs. 186 [160–213], respectively, $p < 0.0001$), medium vs. high (186 [160–213] vs. 204 [180–236], respectively, $p < 0.0001$), and low vs. high (170 [147–197] vs. 204 [180–236], respectively, $p <$

0.0001). Blood loss and postoperative hospital stay also significantly differed by difficulty level (Table 5). The rate of conversion to open surgery was not related to the degree of difficulty. The incidence of complications with Clavien–Dindo classification \geq 3 significantly increased with difficulty.

4. Reliability of the scoring model

In validation set A, the concordance rate

Left hemicolectomy	Sigmoidectomy	High anterior resection	Low anterior resection	All procedure
49	223	112	187	889
205 (179-241)	179 (152-211)	187 (161-222)	200 (180-226)	187 (160-218)
19 (11-34)	7 (4-14)	8 (5-15)	8 (5-17)	10 (5-18)
0 (0.0)	2 (0.9)	0 (0.0)	0 (0.0)	7 (0.8)
8 (7-10)	7 (7-9)	8 (7-10)	10 (8-12)	8 (7-10)
1 (2.0)	5 (2.2)	1 (0.9)	16 (8.6)	30 (3.4)
0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

Estimated surgical duration (min.)

$$= 195.4 + \begin{array}{|l} \text{Sex} \\ \text{Male} : 5.8 \\ \text{Female} : - 5.8 \end{array} + \begin{array}{|l} \text{BMI} \\ < 25 : - 6.0 \\ \geq 25 : 6.0 \end{array} + \begin{array}{|l} \text{Tumor location} \\ \text{Cecum} : - 21.7 \\ \text{Ascending colon} : - 6.3 \\ \text{Transverse colon} : 3.0 \\ \text{Descending colon} : 15.6 \\ \text{Sigmoid colon} : - 11.4 \\ \text{Rectosigmoid colon} : - 4.4 \\ \text{Rectum above the} \\ \text{peritoneal reflection} : 14.0 \\ \text{Rectum below the} \\ \text{peritoneal reflection} : 11.0 \end{array}$$

Fig. 2. The expected surgical duration was calculated by least-squares linear regression analysis. The expected surgical duration (minutes) was calculated by summing 195.4 + the value defined by Sex + the value defined by BMI + the value defined by tumor location.

of the scoring model was 92.1% (Fig. 3). Similarly, the average concordance rate calculated using 10 validation sets for the created scoring model was 92.8%.

IV. Discussion

To date, there have been no indicators guiding case selection for inexperienced surgeons to learn LCCS. The scoring system developed in this study allowed for the stratification of patients into three groups based on three factors: sex, BMI, and tumor location. Ten-fold cross-validation analysis verified the reliability of the scoring system.

Surgical duration, blood loss, and complications increased with increasing surgical difficulty.

Although some studies have used the rate of conversion to open surgery or complications to evaluate surgical difficulty²⁴⁻²⁶⁾, the rate of conversion to open surgery was as low as 0.8%, the amount of blood loss was as low as 10 mL, and there were fewer complications in the present study, as compared to other reports^{16, 27)}. Therefore, the surgical duration was used as the index of surgical difficulty in this study. The reason for the low complication rate seemed to be the presence of endoscopic surgical skill qualification-certified

Table 4. Novel model for difficulty score of laparoscopic colorectal cancer surgery

Sex	Male	11.6
	Female	0.0
BMI	< 25	0.0
	≥ 25	12.0
Tumor location	Cecum	0.0
	Ascending colon	15.4
	Transverse colon	24.7
	Descending colon	37.3
	Sigmoid colon	10.3
	Rectosigmoid colon	17.3
	Rectum above the peritoneal reflection	35.9
	Rectum below the peritoneal reflection	32.7
Total score < 20 : Low difficulty		
20 ≤ Total score < 40 : Medium difficulty		
40 ≤ Total score : High difficulty		

BMI, body mass index

Table 5. Operative outcomes for the three levels of surgical difficulty identified using our scoring model

	Low	Medium	High	p value*		
	difficulty n = 268	difficulty n = 362	difficulty n = 259	L vs M	M vs H	L vs H
Surgical duration (minutes), median (IQR)	170 (147–197)	186 (160–213)	204 (180–236)	< 0.0001	< 0.0001	< 0.0001
Blood loss (mL), median (IQR)	8 (5–16)	10 (5–18)	13 (6–22)	0.3249	0.0036	< 0.0001
Postoperative hospital stay (days), median (IQR)	8 (7–10)	8 (7–10)	10 (8–11)	0.3732	< 0.0001	< 0.0001
Conversion to open surgery, n (%)	2 (0.7)	5 (1.4)	0 (0.0)		0.1576	
Morbidity (Clavien–Dindo grade ≥ 3), n (%)	5 (1.9)	10 (2.8)	15 (5.8)		0.0313	

* Steel–Dwass test for continuous data, and the chi square test for categorical data
IQR, interquartile range; L, low difficulty; M, medium difficulty; H, high difficulty

surgeons at our institution^{17, 28)}, and the use of a standardized surgical technique^{19, 29)}.

Sex, BMI, tumor location, obesity, and locally advanced cancer have all been reported as factors that define surgical difficulty^{24–26, 30, 31)}. In this study, three factors influenced surgical difficulty: sex, BMI, and tumor location. Differences in difficulty based on sex seem to be due to the decrease in operability and

visibility caused by the relatively larger visceral fat area in males³²⁾, and the influence of pelvic volume on the difficulty of rectal cancer surgery^{33, 34)}. During surgery in obese patients with a high BMI score, manipulation of a thickened mesentery and maneuvering of instruments in a restricted area make dissection difficult³⁵⁾. Surgical difficulty is also affected by the tumor location: For instance,

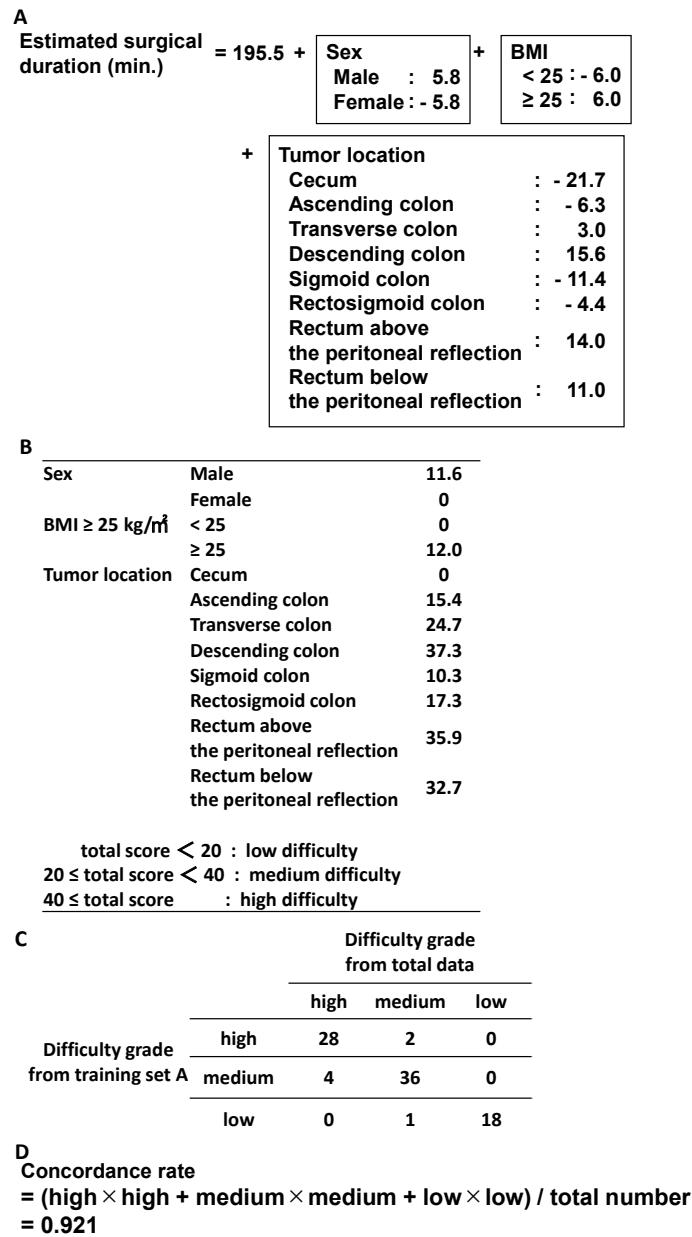


Fig. 3. The concordance rate of the difficulty grade was calculated using validation set A.

- (A) The expected surgical duration in the training set was calculated using least-squares linear regression analysis.
- (B) Created scoring system of the training set from expected surgical duration.
- (C) Difficulty classification table for testing set was created by the difficulty grade from total data and the difficulty grade from training set.
- (D) The concordance rate was calculated as the value that matched in both scoring systems.

the anatomical complexity of blood vessels associated with transverse colon cancer and the difficulty of surgical techniques, such as mobilization of the splenic flexion in descending colon cancer, are likely to

increase the difficulty¹⁰⁻¹²⁾. For rectal cancer, the distance from the anal verge and the size of the tumor affect the difficulty of the procedure³¹⁾. However, in this scoring system, the predicted surgical duration in the rectal

region was longer in the cases involving the rectum above the peritoneal reflection than in the cases involving the rectum below the peritoneal reflection. This may be because tumors at the rectum above the peritoneal reflection required mesorectal dissection as Tumor-Specific Mesorectal Excision.

Differences in the short-term³⁶⁻³⁸⁾ and long-term³⁹⁻⁴¹⁾ outcomes of LCCS have been reported to be influenced by the surgeon's experience and hospital heterogeneity. Similarly, in the JCOG0404 study conducted in Japan, the 5-year survival rate for colon cancer was good in both the open and laparoscopic surgery groups; however, the prognosis for laparoscopic surgery tended to be worse for particular tumor locations, advanced cancer, and obese patients¹²⁾. Thus, experienced surgeons often need to perform difficult LCCS procedures.

In our institution, the surgical procedure is selected according to the Japanese classification and guidelines for colorectal cancer treatment based on tumor location. For decades, D3 dissection, not complete mesocolic excision (CME), has been performed for colorectal cancer in Japan. The superiority of CME with central vascular ligation or D3 dissection for colorectal cancer has not yet been established. Theoretically, the Japanese D3 and CME techniques are equivalent; which of these is more suitable for colorectal cancer surgery remains unclear, and both result in optimal outcomes^{12, 20-22)}. In this study, we evaluated the standard Japanese procedure based on D3 dissection.

With respect to the learning curve for novice surgeons with no experience in LCCS, 30–50 cases should be operated on in order to

master the procedure⁴²⁻⁴⁴⁾. It is important that surgeons gain experience in cases that are appropriate to their proficiency until mastery is achieved. Scoring systems for laparoscopic hepatectomy^{45, 46)} and laparoscopic cholecystectomy⁴⁷⁻⁴⁹⁾ can predict the difficulty of these procedures. Furthermore, scoring systems for laparoscopic rectal cancer surgery⁵⁰⁾ and laparoscopic total mesorectal excision⁵¹⁾ in the colorectal region have been reported. In addition, a scoring system that quantifies the difficulty of each aspect of laparoscopic colorectal surgery (i.e., exposure, dissection, isolation of the vascular pedicle, mobilization of the specimen, and anastomosis), including that for benign diseases⁵²⁾, and a difficulty prediction model that examines the rate of conversion to open surgery^{53, 54)} have been reported. However, no previous study has examined a scoring system for LCCS that considers a number of risk factors affecting surgical difficulty. This scoring system may help in appropriate case selection while relatively inexperienced surgeons learn the LCCS techniques, and is expected to reduce unexpected complications and conversion to open surgery.

Limitations

This study was a single-center retrospective analysis. Thus, it is desirable to validate the scoring system developed in this study using surgical data from other institutions. In addition, we devised a scoring system tailored to case selection for the introduction of LCCS, and the exclusion criteria included highly difficult surgeries. Therefore, we did not consider factors that would make a low anterior resection even more difficult, such

as surgery after chemoradiotherapy. It will be necessary to verify whether case selection using this scoring system can shorten the learning curve and the time required to master surgical techniques and reduce the rate of complications and conversion to open surgery.

In conclusion, we established a scoring system for appropriate case selection for relatively inexperienced surgeons learning the skills to master the technique of LCCS, and it would be useful as an indicator for expanding the application to more difficult cases of LCCS. The consistency of the results was confirmed

by 10-fold cross-validation. This scoring system is likely to improve patient safety through appropriate case selection according to the surgeon's proficiency.

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腹腔鏡下大腸癌手術における 適切な症例選択のための新規スコアリングシステム

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要旨

腹腔鏡下大腸癌手術の習得過程で, 経験の浅い外科医は適切な症例選択が必要である。しかし, その手術難易度を予測する指標はほとんどない。当院で施行した腹腔鏡下大腸癌手術 1390 例を検討し, 手術難易度を予測するスコアリングシステムを構築した。手術難易度の指標を手術時間とし, 難易度に関連する因子を多変量解析で同定し, 線形回帰分析を用いてスコア化した。

性別, body mass index > 25 kg/m², 腫瘍占拠部

位により手術難易度が決定され, これを 3 群に分類した。高難易度群では低・中難易度群に比べて手術時間や入院期間が長く, 出血量が多く, 合併症が多かった。構築したスコアリングシステムの整合性は ten-fold cross-validation により確認した。

構築したスコアリングシステムは腹腔鏡下大腸癌手術の手術難易度を予測することが可能であり, 適切な手術症例の選択に有用であると思われる。