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# Impact of Conversion on Surgical Outcomes after Laparoscopic Operation for Rectal Carcinoma: A Retrospective Study of 1,073 Patients

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- BACKGROUND:** In laparoscopic operations for rectal carcinoma, only a few multicenter studies of a large number of patients have examined the impact of conversion on outcomes and determined risk factors for conversion. This study was designed to evaluate short-term outcomes and risk factors for conversion to open operation in laparoscopic operations for rectal carcinoma.
- STUDY DESIGN:** A total of 1,073 patients with carcinoma of the rectum and anus who underwent laparoscopic operations were reviewed retrospectively. Patients were collected from 28 institutions. Patients who required conversion during laparoscopic operation were compared with those with completed laparoscopic resection.
- RESULTS:** Conversion rate was 7.3% ( $n = 78$ ), and patients requiring conversion were considerably heavier (mean body mass index 24.6 versus 22.7) and had a substantially higher rate of low anterior resection (94.9% versus 83.5%). Conversion was also associated with longer operation time (median 295 minutes versus 270 minutes), greater blood loss (median 265 mL versus 80 mL), longer median postoperative hospital stay (20 days versus 14 days), and higher rates of intraoperative (32.1% versus 3.5%) and postoperative (43.6% versus 21.1%) complications. In multivariate analysis, body mass index and rate of low anterior resection were predictive of conversion.
- CONCLUSIONS:** Conversion to open operation is associated with greater morbidity than completed laparoscopic resection. Body mass index and the particular laparoscopic procedure are risk factors for conversion, indicating that appropriate patient selection is essential in laparoscopic operations for rectal carcinoma. (*J Am Coll Surg* 2009;208:383–389. © 2009 by the American College of Surgeons)
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Controversy still persists about the appropriateness of laparoscopic operations for patients with rectal carcinoma because of the uncertainty of longterm outcomes and concerns about the safety of the procedure. Laparoscopic operations in patients with rectal carcinoma are technically

demanding and persistence with these procedures to avoid conversion to open operation can result in increased rates of complication and mortality.<sup>1-4</sup> Several articles have described a parallel relationship between conversion and complications in laparoscopic operations for colorectal diseases, but others have not found this association.<sup>4-9</sup> In general, the conversion rate for rectal carcinoma is higher than that for colon carcinoma, even if the indication for laparoscopic operation in rectal carcinoma is expanded in a prudent manner, and many reports suggest that rectal carcinoma might be a risk factor for conversion.<sup>1,5,10,11</sup>

For successful laparoscopic operations for colorectal carcinoma, some investigators have reported on risk factors for conversion.<sup>9-13</sup> In laparoscopic operations for rectal carcinoma, there is a concern that short-term and longterm outcomes can be influenced by a lowered immune status if the conversion rate is increased and the complication rate is also increased in parallel. There are few analyses, as for

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**Abbreviations and Acronyms**

BMI	= body mass index
Lap-ISR	= laparoscopic intersphincteric resection
Lap-LAR	= laparoscopic low anterior resection

laparoscopic operations for rectal carcinoma, on the impact of conversion on short-term outcomes and risk factors for conversion in multicenter studies with a large number of patients.<sup>6,11,13</sup> The aim of the current study was to evaluate outcomes in patients requiring conversion compared with those with completed laparoscopic resection using data collected by the Japan Society of Laparoscopic Colorectal Surgery for 1,073 patients with rectal carcinoma who underwent laparoscopic operations.

**METHODS**

The study was performed as a multicenter, retrospective, case-series analysis to evaluate the outcomes of conversion to open operation compared with completed laparoscopic resection and to determine risk factors for conversion in patients with rectal carcinoma. The study was initiated by 28 institutions that are members of the Japan Society of Laparoscopic Colorectal Surgery. All responsible surgeons who participated in the operation as main operator or assistant were skilled in both open and laparoscopic colorectal procedures and had experienced at least 30 laparoscopic operations for colon carcinoma before starting the procedure for rectal carcinoma. A total of 1,073 patients with carcinoma of the rectum and anus, who initially underwent laparoscopic operation during the period between May 1994 and February 2006, were reviewed retrospectively. Clinical, operative, and postoperative data were collected retrospectively.

Tumor location was defined according to the General Rules for Clinical and Pathologic Studies on Cancer of the Colon, Rectum and Anus published by the Japanese Society for Cancer of the Colon and Rectum.<sup>14</sup> Tumors located between the inferior margin of the second sacral vertebra and the peritoneal reflection, below the peritoneal reflection, and mainly located in the anal canal were classified as present in the upper rectum, the lower rectum, and the proctos, respectively. Location of the tumor was determined by pelvic CT scan, colonoscopy, or barium enema preoperatively and confirmed during operation.

The extent of lymphadenectomy and site of ligation and division of the inferior mesenteric vessels were determined by the surgeon in charge. Laparoscopic operations were converted to open operations when the required incision was >8 cm, excluding cases in which the incision was

increased because of a large specimen that could not be removed through an 8-cm incision. Laparoscopic operations were also converted to open operations when open techniques were used to cope with unexpected intraoperative difficulties, regardless of the size of the wound. In laparoscopic low anterior resection (Lap-LAR), the rectum was transected laparoscopically or through a small laparotomy; this decision was made by the surgeon. There were no guiding principles for conversion and the decision to convert was at the discretion of the surgeon.

To investigate risk factors for intraoperative conversion, all clinical data collected, including gender, age, body mass index (BMI), tumor location from the anal verge, location of the tumor, laparoscopic procedures, size of tumor, distal margin, resected lymph nodes, and pTNM stage were evaluated. Operative data included operation time, blood loss, length of incision, intraoperative complications, and reasons for conversion to open operation. Postoperative data included time until resumption of liquid and solid intake, postoperative hospital stay, morbidity, 30-day mortality, and reasons for reoperation. Data on combined operations were included in the analyses of laparoscopic operations for rectal carcinoma.

Statistical analysis was performed using SPSS version 11.0 software. In univariate analysis, Student's *t*-test and Fisher's exact test were used as appropriate. Multivariate analysis was performed by logistical regression using independent variables, with a *p* value <0.2 in univariate analysis. Initially, BMI, laparoscopic procedure, pTNM stage, and location of the tumor were selected as variables because these variables had *p* values <0.2 in univariate analysis; but the laparoscopic procedure and tumor location were correlated (rate of LAR in the upper rectum versus lower rectum and proctos, 98.5% [659 of 669] versus 60.9% [246 of 404], respectively (*p* < 0.0001), and the location of the tumor was excluded from multivariate analysis because the *p* value of the tumor location in univariate analysis was higher than that for the laparoscopic procedure. In multivariate analysis, data about the laparoscopic procedure were combined into two categories (low anterior resection versus others), and data about the pTNM stage were combined into two categories (0 + I versus II + III + IV). A *p* value <0.05 was considered significant.

A forward or backward selection procedure was not used in the present study.

**RESULTS**

Patient demographics are summarized in Table 1. The observed conversion rate was 7.3% (*n* = 78), and patients requiring conversion were considerably heavier (mean BMI 24.6 versus 22.7) and had a substantially higher rate

**Table 1.** Characteristics of 1,073 Patients Who Underwent Converted or Laparoscopic Rectal Resection

	Converted (n = 78)	Laparoscopic (n = 995)	p Value
Gender (male/female)	48/30	625/370	0.809
Age (y), mean (range)	63.8 (38–81)	62.9 (24–94)	0.504
Body mass index,* mean (range)	24.6 (16.6–34.8)	22.7 (13.7–36.7)	<0.0001
Tumor location from anal verge (cm), median (range)	10.0 <sup>†</sup> (2–15)	8.0 <sup>‡</sup> (0–18)	0.992
Location, n (%)			
Upper rectum	57 (73)	611 (61)	
Lower rectum	21 (27)	362 (36)	
Proctos	0	22 (2)	
Ratio of upper rectum to lower rectum + proctos	57:21	611:384	0.052
Laparoscopic procedures, n (%)			
Low anterior resection	74 (95)	831 (84)	
Intersphincteric resection	1 (1)	49 (5)	
Abdominoperineal resection	3 (4)	104 (10)	
Hartmann	0	10 (1)	
Total pelvic exenteration	0	1 (0.1)	
Ratio of low anterior resection to others	74:4	831:164	0.005
Size of tumor (mm), mean (range)	35 <sup>†</sup> (8–110)	35 <sup>§</sup> (4–135)	0.732
Distal margin (mm), mean (range)	27 (3–70)	26 <sup>†</sup> (0–120)	0.573
Lymph nodes resected, median (range)	16 (0–84)	15 <sup>†</sup> (0–52)	0.260
pTNM stage, n (%)			
0	5 (6)	91 (9)	
I	32 (41)	463 (47)	
II	15 (19)	183 (18)	
III	21 (27)	211 (21)	
IV	5 (6)	47 (5)	
Ratio of 0 + I to II + III + IV	37:41	554:441	0.193

\*Calculated as kg/m<sup>2</sup>.<sup>†</sup>Data are missing for one patient.<sup>‡</sup>Data are missing for three patients.<sup>§</sup>Data are missing for seven patients.

of LAR (94.9% versus 83.5%) compared with those with completed laparoscopic resection. There were no other substantial differences in baseline characteristics between patients with and without conversion and tumor characteristics were similar. Median followup period was 26 months (range 0 to 140 months). One patient received preoperative chemotherapy, two underwent preoperative radiotherapy, and three received preoperative chemoradiotherapy.

None of these patients required conversion. In Lap-LAR, the rectum was transected laparoscopically in 625 patients and through a small laparotomy in 274 patients; data were missing for 6 patients.

For operative and postoperative results (Table 2), conversion was associated with a substantially longer operation time, greater blood loss, and longer incision. Liquid and solid foods were also started considerably later in patients

**Table 2.** Operative and Postoperative Results of Patients Who Underwent Converted or Laparoscopic Rectal Resection

	Converted (n = 78)		Laparoscopic (n = 995)		p Value
	Median	Range	Median	Range	
Operative time (min)	295	138–630	270	80–780	0.007
Blood loss (mL)	265	4–1,800	80	2–1,500	<0.001
Length of incision (cm)	12	3.5–40	5*	0–13	<0.001
Postoperative days of liquid intake	3	1–53	2*	1–70	0.002
Postoperative days of solid food intake	5	2–54	4*	1–83	<0.001
Postoperative hospital stay (d)	20	7–161	14*	6–271	0.010

\*Data are missing for one patient.

**Table 3.** Intraoperative Complications in Patients Who Underwent Converted or Laparoscopic Rectal Resection

	Converted (n = 78)		Laparoscopic (n = 995)	
	n	%	n	%
Difficulty in rectal transection	9	11	4	0.4
Problems with anastomosis	7	9	7	0.7
Organ injury	6	8	11	1.1
Inferior mesenteric artery	3			
Rectum	2		2	
Small intestine	1		2	
Ureter			3	
Hypogastric nerve			1	
Vaginal wall			1	
Unknown			2	
Hemorrhage	3	4	10	1.0
Inadequate distal margin			2	0.2
Unknown			1	0.1
Total patients with intraoperative complication	25*	32	35*	3.5

\* $p < 0.0001$ .

who required conversion and again conversions were associated with a substantially longer postoperative hospital stay (median 20 versus 14 days).

Intraoperative complications are shown in Table 3. The most common intraoperative complication in patients who required conversion was difficulty in rectal transection (11.5%), followed by problems with anastomosis (8.9%), organ injury (7.7%), and hemorrhage (3.8%). The most common intraoperative complication in the laparoscopic completed group was organ injury (1.1%), followed by hemorrhage (1.0%), problems with anastomosis (0.7%), and difficulty in rectal transection (0.4%). Conversions were associated with a considerably higher rate of intraoperative complications than the laparoscopic completed group.

Postoperative complications are shown in Table 4. The most common postoperative complications in patients who required conversion were wound sepsis and anastomotic leakage (17.9%), followed by bowel obstruction (10.3%). The most common postoperative complication in the laparoscopic completed group was anastomotic leakage (7.2%), followed by wound sepsis (5.6%) and bowel obstruction (3.0%). Morbidity rate was considerably higher in patients requiring conversion (43.6% [34 of 78] versus 21.1% [210 of 995], respectively). There were no perioperative mortalities.

The most common reasons for conversion to open operation was advanced tumors (n = 13), followed by obesity (n = 12), adhesion (n = 10), difficulty in rectal transection (n = 9), problems with anastomosis (n = 7), organ injury (n = 5), difficulty in judging the tumor location (n = 5), difficulty in laparoscopic pelvic view (n = 5), anesthesia

(n = 3), hemorrhage (n = 2), other technical problems (n = 4), and unknown (n = 3). For conversions related to obesity, median BMI was 28.4 (range 24.8 to 34.8). Rates of reoperation were similar for patients who did and did not require conversion (6.4% [5 of 78] versus 5.2% [52 of 995], respectively;  $p = 0.600$ ). Reasons for reoperations in patients who required conversion were anastomotic leakage (n = 3) and bowel obstruction (n = 2). Reasons for reoperations in patients who did not require conversion were anastomotic leakage (n = 38), followed by bowel obstruction (n = 4), port-site hernia (n = 2), abscess (n = 2), anastomotic bleeding (endoscopic clipping) (n = 2), hemorrhage (n = 1), perforation of small intestine (n = 1), inguinal hernia incarceration (n = 1), and unknown (n = 1).

Multivariate analysis (Table 5) showed that BMI (odds ratio = 1.176) and the laparoscopic procedure (LAR versus other, odds ratio = 3.386) were predictive factors of conversion.

## DISCUSSION

This study demonstrated that conversion to open operation in laparoscopic rectal resection is associated with substantially greater morbidity compared with completed laparoscopic resection, and that BMI and laparoscopic procedure (rate of LAR) are predictive of conversion. This is the first study of a large number of patients to suggest that conversion has negative effects on short-term outcomes in rectal carcinoma, and our findings show that the indication for laparoscopic procedure should be determined carefully for obese patients undergoing Lap-LAR.

Conversion rate of 7.3% (78 of 1,073) in the present

**Table 4.** Morbidities and Mortality in Patients Who Underwent Converted or Laparoscopic Rectal Resection (within 30 Days)

	Converted (n = 78)		Laparoscopic (n = 995)	
	n	%	n	%
Mortality	0		0	
Morbidity				
Wound sepsis	14	18	56	5.6
Anastomotic leakage	14	18	72	7.2
Bowel obstruction	8	10	30	3.0
Cholecystitis	1	1		
Urinary tract infection	1	1	2	0.2
Anastomotic bleeding	1	1	6	0.6
Decubitus	1	1		
Catheter infection	1	1		
Muscle weakness	1	1		
Neurogenic bladder			13	1.3
Abscess			13	1.3
Hemorrhage			9	0.9
Median, ulnar nerve palsy			6	0.6
Pneumonia			5	0.5
Enterocolitis			5	0.5
Chylous ascites			4	0.4
Liver dysfunction			3	0.3
Port site hernia			2	0.2
Drainage tube infection			2	0.2
Rectovaginal fistula			2	0.2
Duodenal ulcer hemorrhage			2	0.2
Pneumothorax			1	0.1
Cerebral infarction			1	0.1
Port-site hematoma			1	0.1
Peritonitis			1	0.1
Inguinal hernia incarceration			1	0.1
Anastomotic stenosis			1	0.1
Enterocutaneous fistula			1	0.1
Total complications	42	54	239	24
Total patients with complication*	34	44	210	21

\*p &lt; 0.001.

study was lower than those reported for rectal carcinoma in previous studies.<sup>11,13,15,16</sup> This lower conversion rate might be a result of the lower number of obese patients in Japan compared with Western countries. The rate might also have been reduced by selection of patients with relatively early-

stage rectal carcinoma as candidates for laparoscopic operation because patients with a preoperative diagnosis of T3 lower rectal carcinoma are not usually indicated for laparoscopic procedures in Japan because of the increased technical difficulty of laparoscopic operations in these patients.<sup>17</sup> In addition, open lateral lymph node dissection combined with total mesorectal excision without radiation therapy remains the standard treatment for patients with advanced lower rectal carcinoma in Japan, and lateral lymph node dissection by laparoscopy is still an unexplored frontier. Another factor that might have influenced the conversion rate is the difference in treatment strategies in Japan and Western countries. Neoadjuvant radiotherapy is not routinely performed in Japan, partly because of short- and long-term adverse effects and also because the local recurrence rate without radiotherapy in Japan is comparable with that of Western countries with neoadjuvant radiochemotherapy, and clearly such therapy increases the difficulty of subsequent operations.

We found a higher complication rate in patients who required conversion to open operation in laparoscopic rectal resection. In the present study, timing of conversion was not examined, but the considerably longer total operation time for these patients compared with those with completed laparoscopic resection indicates that timing of conversion might be delayed because of the surgeons' attempt to complete the operation laparoscopically. For a patient in whom laparoscopic operation is considered to be difficult intraoperatively, "early" conversion to open operation is recommended before a critical complication occurs, rather than trying to decrease the conversion rate by completing the laparoscopic operation by any means.<sup>4,13</sup>

Interestingly, the percentage of Lap-LAR procedures in patients requiring conversion was substantially higher than in those with completed laparoscopic resection. In addition, the conversion rate in patients treated with laparoscopic intersphincteric resection (Lap-ISR) was lower than that in patients treated with Lap-LAR (2.0% [1 of 50] versus 8.2% [74 of 905]). ISR for rectal carcinoma has been developed more recently, and this procedure requires intersphincteric dissection and per-anum anastomosis.<sup>18,19</sup> In open operations, ISR is considered to be a more demanding operation than LAR; but from the perspective of conversion, Lap-LAR can be more demanding than Lap-ISR.

**Table 5.** Independent Predictors of Intraoperative Conversion Identified by Multivariate Analysis

	Odds ratio	95% CI	Test statistic	Degree of freedom	p Value
Body mass index*	1.176	1.090–1.261	21.10	1	<0.0001
Laparoscopic procedures	3.386	1.211–9.470	7.55	1	0.0201
pTNM stage	1.556	0.971–2.492	3.39	1	0.0660

\*Calculated as kg/m<sup>2</sup>.

Laurent and colleagues<sup>13</sup> reported a similar finding in a study of conversion rates in laparoscopic reconstruction after total mesorectal excision, with rates of 11.6% and 22% for hand sewn and stapled anastomosis, respectively; but the low conversion rate in Lap-ISR does not mean it is a relatively easy procedure. In the present study, there is a possibility that only laparoscopic surgeons with experience performed Lap-ISR, and the number of Lap-ISR in the present study is too small to reach a conclusion. It goes without saying that Lap-ISR should be performed with extreme care.

The design of the study is limited because all data were collected retrospectively and only a few variables were examined as potential risk factors of conversion. Results serve as a caution against unlimited expansion of the indication of laparoscopic operations for rectal carcinoma. Based on these results, a phase II trial to examine the technical and oncological feasibility of laparoscopic operations for rectal carcinoma in patients with a preoperative diagnosis of stage 0/I rectal carcinoma has been initiated under the direction of the Japan Society of Laparoscopic Colorectal Surgery, in which leading hospitals in laparoscopic procedures for colorectal carcinoma in Japan participate.<sup>20,21</sup> Given the importance of verifying the safety of laparoscopic procedures, we believe their use for rectal carcinoma is just beginning to be evaluated.

In conclusion, conversion to open operation in laparoscopic rectal resection is associated with considerably greater morbidity compared with completed laparoscopic resection. BMI and the laparoscopic procedure (rate of LAR) are risk factors for conversion. Appropriate patient selection is important for laparoscopic operation for rectal carcinoma, and particularly for a Lap-LAR procedure for an obese patient. In addition, laparoscopic surgeons should recognize that the purpose of laparoscopic operation is not to decrease the conversion rate by completing the laparoscopic procedure by any means, and early conversion is recommended in patients for whom a laparoscopic procedure is considered difficult intraoperatively.

### Author Contributions

Study conception and design: Yamamoto, Konishi, Watanabe

Acquisition of data: Yamamoto, Fukunaga, Miyajima, Okuda, Konishi, Watanabe

Analysis and interpretation of data: Yamamoto, Watanabe

Drafting of manuscript: Yamamoto, Watanabe

Critical revision: Yamamoto, Konishi, Watanabe

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## Laparoscopic Surgery for Transverse and Descending Colon Carcinomas Has Comparable Safety to Laparoscopic Surgery for Colon Carcinomas at Other Sites

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### Key Words

Transverse colon carcinoma · Descending colon carcinoma · Colon carcinoma

### Abstract

**Background/Aims:** Many randomized clinical trials have been performed to treat colon carcinoma with the exclusion of transverse colon carcinoma or descending colon carcinoma. The aim of the present study was to investigate the difference in surgical outcomes between laparoscopic surgery for transverse/descending colon carcinomas and that for other colon carcinomas. **Methods:** A total prospective registry of 455 patients with colon carcinoma, who initially underwent laparoscopic surgery between June 2001 and December 2008, were reviewed. Surgical outcomes were compared between laparoscopic surgery for transverse/descending colon carcinoma (transverse/descending group, n = 89) and laparoscopic surgery for other colon carcinomas (other group, n = 366). **Results:** There was no perioperative mortality. Preoperative clinical characteristics were similar between the two groups. Regarding operative and postoperative results, the surgical duration and intraoperative blood loss were significantly greater in the transverse/descending group. However, there were no significant differences in the postoperative course between groups, and the complica-

tion rates between the groups were similar. **Conclusion:** Laparoscopic surgery for transverse/descending carcinoma can be performed safely, and shows short-term benefits comparable to those in patients who underwent laparoscopic surgery for other colon carcinomas.

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### Introduction

The application of laparoscopic surgery has gradually increased since the first report of laparoscopic surgery for colon carcinoma in 1991 [1]. Long-term oncological safety is an important concern following laparoscopic surgery for malignancies, and in this respect laparoscopic surgery is at least equivalent to conventional open surgery based on randomized clinical trials; however, many of these trials have been performed to treat colon carcinoma with the exclusion of transverse colon carcinoma or transverse colon and descending colon carcinoma, which require relatively advanced surgical skills [2–8]. In Japan, patients with transverse colon or descending colon cancer were excluded from the randomized control trial (JCOG 0404), and we believe that evaluation of the surgical outcomes of laparoscopic surgery for these patients is necessary. These exclusions have been made because of

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safety concerns, i.e. the risk of complications associated with the laparoscopic procedure.

Several recent prospective case series studies of laparoscopic surgery for transverse colon carcinoma have demonstrated the safety of the procedure [9, 10]. In Japan, a prospective randomized clinical trial comparing surgical and oncological outcomes between laparoscopic surgery and open surgery is currently underway in patients with clinical T3 or T4 colon and rectosigmoid carcinoma; however, patients with transverse colon and descending colon carcinoma have been excluded from this Japanese trial for technical reasons [8]. Therefore, the current study was designed to compare surgical outcomes between laparoscopic surgery for transverse colon and descending colon carcinomas and that for other colon carcinomas, in the absence of randomized clinical trials comparing laparoscopic and open surgery for transverse colon and descending colon carcinoma.

## Material and Methods

The study took the form of a single-center, prospective, observational, case-series analysis. Between July 2001 and December 2008, we performed 455 continuous laparoscopic colectomies for selected patients with colon carcinoma. Because the safety of laparoscopic surgery in cancer patients remains to be established, candidates for a radical surgery were basically patients who were preoperatively diagnosed with T1 or T2. Laparoscopic surgery was also performed in patients who were preoperatively diagnosed with T3/4 but wished to undergo laparoscopic surgery as well as in those for which palliative resection was considered necessary. Additionally, patients allocated to laparoscopic surgery in a randomized controlled trial, which compared the surgical results of laparoscopic surgery to open surgery in patients with advanced colorectal carcinoma, underwent laparoscopic surgery [8]. We excluded the following groups of patients from laparoscopic resection: patients with tumors larger than 8 cm, patients with a prior history of extensive adhesions, patients with severe obesity (BMI >35), patients with intestinal obstruction, and patients who did not consent to laparoscopic surgery. During the study period, we experienced 2 patients who underwent two simultaneous laparoscopic colectomies for synchronous double colon carcinomas, and these 2 patients were excluded from the study.

Surgical outcomes were compared between laparoscopic surgery for transverse colon and descending colon carcinoma (transverse/descending group,  $n = 89$ ) and laparoscopic surgery for other colon carcinomas (other group,  $n = 366$ ).

All patients were evaluated before operation by clinical investigation, including barium enema or computed tomographic colonography, total colonoscopy, chest X-ray, abdominal ultrasonography and computed tomography. We defined conversion to open surgery as any incision greater than 8 cm, excluding cases in which the incision was enlarged due to a large specimen size that could not be removed from an 8-cm incision.

Regarding a postoperative follow-up, patients with stage I tumors were examined by chest and abdominopelvic CT, as well as carcinoembryonic antigen measurement every year for at least 5 years. Patients with stage II tumors were examined every 6 months for 3 years, then yearly for at least 2 years. Patients with stage III tumors were examined every 4 months for 2 years, then every 6 months for at least 3 years. Postoperatively, patients with stage III received adjuvant chemotherapy with 5-fluorouracil plus leucovorin or uracil-tegafur plus leucovorin.

Our institutional review board does not mandate obtaining their approval for the collection of patient clinical records prospectively and for publication as an institutional case-series study, and written consent was obtained from all patients for the use of their clinical data in the future.

The techniques of laparoscopic resections have been thoroughly described previously [11, 12].

For right-sided lesions, the right colon was mobilized initially, and the vascular pedicles were divided at their origin together with draining lymph nodes intracorporeally. From 2004, the laparoscopic no-touch isolation technique, so-called 'median-to-lateral' approach, was performed. In this technique, after early proximal ligation of the tumor-feeding vessels and mobilization of the right colon from median-to-lateral direction, mobilization was completed by cutting the peritoneum from the lateral side. The bowel loop was then delivered under a wound protector through a small incision. The division of the marginal vessels and anastomosis were performed extracorporeally.

For transverse colon lesions, at least, mobilization of the hepatic flexure or splenic flexure or both flexures was performed according to the tumor location. Mobilization of both flexures was performed without hesitation to avoid tension on the anastomosis. Proximal ligations of the right or left branch or the root of middle colic vessels at their origins were usually, but not always, performed intracorporeally. Usually, right hemicolectomy was performed for tumors located from the hepatic flexure to one-third on the right side of transverse colon. Regarding middle colic vessel ligation for right hemicolectomy, the root of the right branch of the middle colic artery or origin of the middle colic artery was confirmed and clipped after proximal ligation of ileocolic and right colic vessels by the median-to-lateral approach. Usually, the middle colic vein is clipped just before it is drained into the gastrocolic trunk. For tumors located from the splenic flexure to one-third on the left side of transverse colon, partial resection of transverse colon and descending colon was performed. In this procedure, the root of the left branch of middle colic vessels is skeletonized in a caudal to cranial direction, and clipped. For mid-transverse tumors, partial resection or transverse colectomy was performed. A transverse colectomy was defined as a procedure with mobilization of both the hepatic and splenic flexure together with ligation of the middle colic vessels at their origin. In this procedure, the middle colic artery is skeletonized in a caudal to cranial direction, and clipped at the origin, or both branches of the middle colic artery are clipped at or near their roots. Similarly, the middle colic vein is clipped just before it is drained into the gastro-colic trunk, or at the same level of both branches of the middle colic artery. Sometimes, endolinear staplers are used for the division of right or left branches of middle colic vessels.

For descending colon and proximal sigmoid colon lesions in which extracorporeal anastomosis was considered possible, the

left colon was mobilized initially. After mobilization of the splenic flexure, intracorporeal ligation of the tumor-feeding vessels (left colic artery, sigmoid arteries, inferior mesenteric vein) at their origins was performed, and the bowel loop was delivered through a small incision and the mesentery was divided extracorporeally followed by extracorporeal anastomosis.

For distal sigmoid colon lesions, after mobilization of the left colon and splenic flexure if necessary, intracorporeal high ligation of the inferior mesenteric vessels followed by mobilization of the rectum and excision of the mesorectum were performed. From 2004, the median-to-lateral approach was also employed. In this technique, after early proximal ligation of the tumor-feeding vessels (inferior mesenteric artery or superior rectal artery, and inferior mesenteric vein), mobilization of the left colon was performed from the median-to-lateral direction. After the completion of full mobilization by cutting the peritoneum from the lateral side, the bowel loop was delivered through a 4- to 8-cm incision made over the mid-lower port site under wound protection and the mesentery was divided extracorporeally followed by extracorporeal anastomosis. For patients with sigmoid colon carcinoma located near the rectosigmoid junction, mobilization of the rectum and excision of the mesorectum were performed intracorporeally by laparoscopic surgery. A 4- to 6-cm incision was then made over the mid-lower port site, and the bowel was exteriorized under wound protection. Regarding the distal margin, mesorectal tissue down to at least 5 cm below the tumor was excised routinely. Anastomosis was performed by the double-stapling technique.

In all cases, the retroperitoneum was not repaired.

The parameters analyzed included gender, age, body mass index, prior abdominal surgery, ASA classification, simultaneous procedures, operative time, operative blood loss, conversion rate, days to resume diet, length of postoperative hospital stay, and postoperative complications within 30 days of operation. Pathological staging was performed according to the TNM classification [13].

Data on combined surgical techniques were all included in the analyses of colon carcinoma surgeries.

Statistical analysis was performed using the Mann-Whitney U test, the Fisher's exact test, and the  $\chi^2$  test as appropriate.  $p < 0.05$  was considered significant.

## Results

Patient demographics are summarized in table 1. No significant differences were observed in baseline characteristics between the two groups. With regard to combined surgical techniques, 5 patients in the transverse/descending group and 12 patients in the other group underwent combined surgery ( $p = 0.3458$ ).

Operative and postoperative results are shown in table 2. All operations in the other group were completed laparoscopically in this series; however, 1 patient (1/89, 1.1%) in the transverse/descending group with transverse colon carcinoma required conversion to conventional

open surgery because of tumor invasion to the duodenum. The surgical duration and intraoperative blood loss were significantly longer in the transverse/descending group; however, liquid and solid food was started on median postoperative days 1 and 3 in both groups. Similarly, the median length of postoperative hospitalization was 8 days in both groups. No significant differences were observed in the postoperative course between the two groups. All patients were discharged to home.

Postoperative complications within 30 days after initial operation are listed in table 3. There were no perioperative mortalities. The morbidity rate was 14.6% (13/89) in the transverse/descending group, and 10.9% (40/366) in the other group ( $p = 0.3571$ ). In the transverse/descending group, one patient required readmission 23 days after initial operation because of duodenal ulcer perforation, which could be treated conservatively. In the other group, anastomotic leakage occurred in 1 patient, and emergency operation was required. Reoperation of laparoscopic division of an adhesive band for a postoperative small bowel obstruction was necessary in another patient. For 2 patients with anastomotic bleeding after double-stapling technique anastomosis, endoscopic clipplings were performed successfully.

## Discussion

In the present study, short-term outcomes after laparoscopic surgery were compared between the transverse/descending group and other group. The operative time was significantly longer and the intraoperative blood loss was significantly greater in the transverse/descending group, but the complication rates and postoperative courses of the two groups were similar and there was no anastomotic leakage in the transverse/descending group. The observed safety of laparoscopic surgery for patients with transverse colon and descending colon carcinoma may be due to improved instruments and the proficiency of surgeons.

The design of the present study was limited in that laparoscopic surgery was not compared with open surgery, the patients were in relatively early stages, and the long-term prognosis was unknown in many cases. In the previous randomized clinical trials comparing surgical outcomes between laparoscopic surgery and open surgery, patients with transverse colon and descending colon carcinoma have been excluded [2–8]. It goes without saying that prospective randomized clinical trial is ideal to demonstrate that short-term and oncological outcomes

**Table 1.** Characteristics of 455 colon carcinoma patients who underwent laparoscopic resection

	Transverse/ descending group (n = 89)	Other group (n = 366)	p value
Gender (male/female)	55/34	204/162	0.3402
Age, years (mean, range)	61.4 (22–83)	62.7 (22–88)	0.3479
BMI (mean, range)	23.1 (16.8–32.3)	22.8 (14.0–34.6)	0.6004
Prior abdominal surgery, %	23 (25.8)	101 (27.6)	0.7918
ASA classification, %			0.3618 <sup>a</sup>
ASA I	52 (58)	214 (58)	
ASA II	24 (27)	116 (32)	
ASA III	13 (15)	36 (10)	
TNM classification, %			0.3875 <sup>b</sup>
I	58 (65)	211 (58)	
II	9 (10)	54 (15)	
III	19 (21)	77 (21)	
IV	3 (3)	24 (7)	
Location, %			
Vermiform appendix	0	2 (1)	
Cecum	0	57 (16)	
Ascending colon	0	88 (24)	
Transverse colon	55 (62)	0	
Descending colon	34 (38)	0	
Sigmoid colon	0	219 (60)	
Laparoscopic colorectal procedures, %			
Ileocecal resection	0	61 (17)	
Right hemicolectomy	24 (27)	86 (23)	
Transverse colectomy	3 (3)	0	
Left hemicolectomy	4 (4)	0	
Descending colectomy	22 (25)	0	
Sigmoid colectomy	0	200 (55)	
Partial resection	36 (40)	19 (5)	
Combined surgical techniques, n			0.3458
Cholecystectomy	1	3	
Umbilical hernia repair	1	0	
Nephroureterectomy	1	0	
Hemilateral neck lymph node dissection	1	0	
Total laryngectomy	1	0	
Pulmonary resection	0	2	
Unilateral salpingo-oophorectomy	0	2	
Partial mastectomy	0	1	
Wedge resection of gastric submucosal tumor	0	1	
Resection of submandibular gland tumor	0	1	
Resection of ileum tumor	0	1	
Inguinal hernia repair	0	1	

$\chi^2$  value: <sup>a</sup> 2.0331, <sup>b</sup> 3.0268.

of laparoscopic surgery are not inferior to those of open surgery in patients with transverse colon and descending colon carcinoma; however, the incidence of transverse colon and descending colon carcinoma is low among colon carcinomas, which makes it difficult to conduct randomized clinical trial with an endpoint of long-term out-

come due to the lack of a sufficient number of patients. In these circumstances, the outcome of laparoscopic surgery for transverse colon and descending colon carcinoma was compared with that for laparoscopic surgery for other colon carcinomas in the present study to show the efficacy of laparoscopic surgery in selected patients. Con-

**Table 2.** Operative and postoperative results of patients who underwent laparoscopic resection

	Transverse/descending group (n = 89)		Other group (n = 366)		p value
	median	range	median	range	
Operative time, min	220	95-615	195	95-400	0.0135
Blood loss, ml	42	2-365	25	2-753	0.0165
Liquid intake, days	1	1-13	1	1-4	0.5552
Solid food, days	3	2-14	3	2-7	0.8111
Hospital stay, days	8	5-20	8	5-28	0.6824

**Table 3.** Morbidities and mortality in patients who underwent laparoscopic resection (within 30 days)

	Transverse/descending group (n = 89)		Other group (n = 366)	
	n	%	n	%
Mortality	0	0	0	0
Morbidity				
Wound sepsis	5	6	22	6
Bowel obstruction	5	6	4	1
Pneumonia	1	1	2	0.5
Perforation of duodenal ulcer	1	1	0	0
Pulmonary embolism	1	1	0	0
Urinary tract infection	0	0	7	2
Anastomotic bleeding	0	0	2	0.5
Anastomotic leakage	0	0	1	0.3
Gastric ulcer bleeding	0	0	1	0.3
Pneumothorax	0	0	1	0.3
Enterocolitis	0	0	1	0.3
Subcutaneous hematoma	0	0	1	0.3
Total complications	13	15	42	11
Total patients with complication*	13	15	40	11

\* p = 0.3571.

firmation of the safety of the laparoscopic approach will require further accumulation of patients.

The most significant technical issue in laparoscopic surgery for transverse colon and descending colon carcinoma may be the division of supplying arteries and drainage veins. Tumor-supplying vessels differ depending on the location of the tumor. Moreover, special attention is necessary to cope with the wide variations of these vessels, especially middle colic arteries and veins [14, 15]. Initially, supplying vessels were routinely divided after mobilization of the colon by laparoscopic surgery in our department; however, we currently use a median-to-lat-

eral approach, in which the supply vessels are ligated first [11]. This approach enables easier division of blood vessels in many cases and may reduce the spillage of isolated tumor cells into the blood stream, although there is no clear evidence for this. However, the division of middle colic vessels before the mobilization of hepatic or splenic flexure is still a technically demanding procedure in laparoscopic surgery for transverse colon carcinoma, and it may be better to ligate these vessels when it can be done most easily, regardless of the timing with respect to mobilization.

Fortunately, the complication rates and postoperative course were similar in the two groups in the present study, but the incidence of postoperative bowel obstruction in the transverse/descending group (5/89, 6%) was higher than in the other group (4/366, 1%). Although a successful conservative treatment was performed in all 5 patients in the transverse/descending group, one patient in the other group required laparoscopic division of an adhesive band for a postoperative small bowel obstruction. Interestingly, all 5 patients who developed postoperative bowel obstruction in the transverse/descending group were patients with transverse colon carcinoma, and right hemi-colectomy was conducted in two and partial resection in three. In previous studies, the incidence of postoperative bowel obstruction after laparoscopic surgery in transverse colon carcinoma has been found to be 2- to 3-fold higher than in other colon carcinomas [9, 10]. Regarding this aspect, data collection from more patients is essential before making decisions; however, the possibility of increased postoperative bowel obstruction should always be kept in mind after laparoscopic surgery for transverse colon carcinoma.

The mean operative time in the present study was slightly longer than in previous studies of laparoscopic surgery. This may have been partly due to an increased proportion of patients in relatively advanced stages, and also because, in many cases, trainee doctors performed

part or all of the surgical procedures under the guidance of staff doctors. Our hospital is an educational institution and the rate of laparoscopic surgery for colon carcinoma conducted by trainee doctors has been increasing as laparoscopic surgery has become more common in Japan; however, the results of the present study indicate that the quality of our surgical procedures has not been lowered.

In conclusion, laparoscopic surgery for transverse colon and descending colon carcinoma can be performed safely without increased morbidity or mortality, and shows short-term benefits comparable to those after laparoscopic surgery for other colon carcinomas. Considering that conducting a new randomized clinical trial targeting these patients is virtually difficult, the safety of this procedure requires confirmation through the accumulation of more patients prospectively.

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## REVIEW ARTICLE

**Laparoscopic colorectal cancer surgery: Japanese experience**F Konishi<sup>1</sup>, Y Kawamura<sup>1</sup>, S Kitano<sup>2</sup>, T Kimura<sup>3</sup> & M Watanabe<sup>4</sup><sup>1</sup> Department of Surgery, Saitama Medical Center, Jichi Medical University, Saitamaken, Japan<sup>2</sup> Department of Surgery, Faculty of Medicine, Oita University, Oita, Japan<sup>3</sup> Department of Surgery, Fujinomiya City Hospital, Fujinomiya, Japan<sup>4</sup> Department of Surgery, Kitasato Medical University, Kanagawa, Japan**Keywords**

Colorectal cancer; laparoscopic colectomy; randomized controlled trial

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**Abstract**

In Japan, laparoscopic colectomy for cancer started in 1992. A national survey has revealed that, since that time, the number of cases that have undergone this procedure has steadily increased, and by 2007, there were over 9000 cases. This figure includes an increase in the percentage of more advanced cases, which has occurred due to technical improvements in lymph node dissection.

A Japanese randomized controlled trial comparing laparoscopic to open surgery started in November 2004, with enrollment ending in April 2009 with 1050 cases. For this study, preoperative stage T3 and T4 cases were selected for inclusion, and D3 dissection was required.

To assess the technical skill of surgeons, the Japan Society of Endoscopic Surgery established the Endoscopic Surgical Skill Qualification System to encourage high-level surgical techniques. Assessment is conducted by reviewing unedited videos. The success rate for colon and rectal surgeries has ranged between 37%–40%. The Endoscopic Surgical Skill Qualification System has contributed to the establishment of standard technical skills in laparoscopic surgery, the development of an educational system for laparoscopic surgeons, and a reduction in the number complications. Technical difficulties still exist in laparoscopic rectal cancer surgery, but with the technical progress in laparoscopic colorectal surgery, the number of laparoscopic rectal cancer surgeries has been gradually increasing in number.

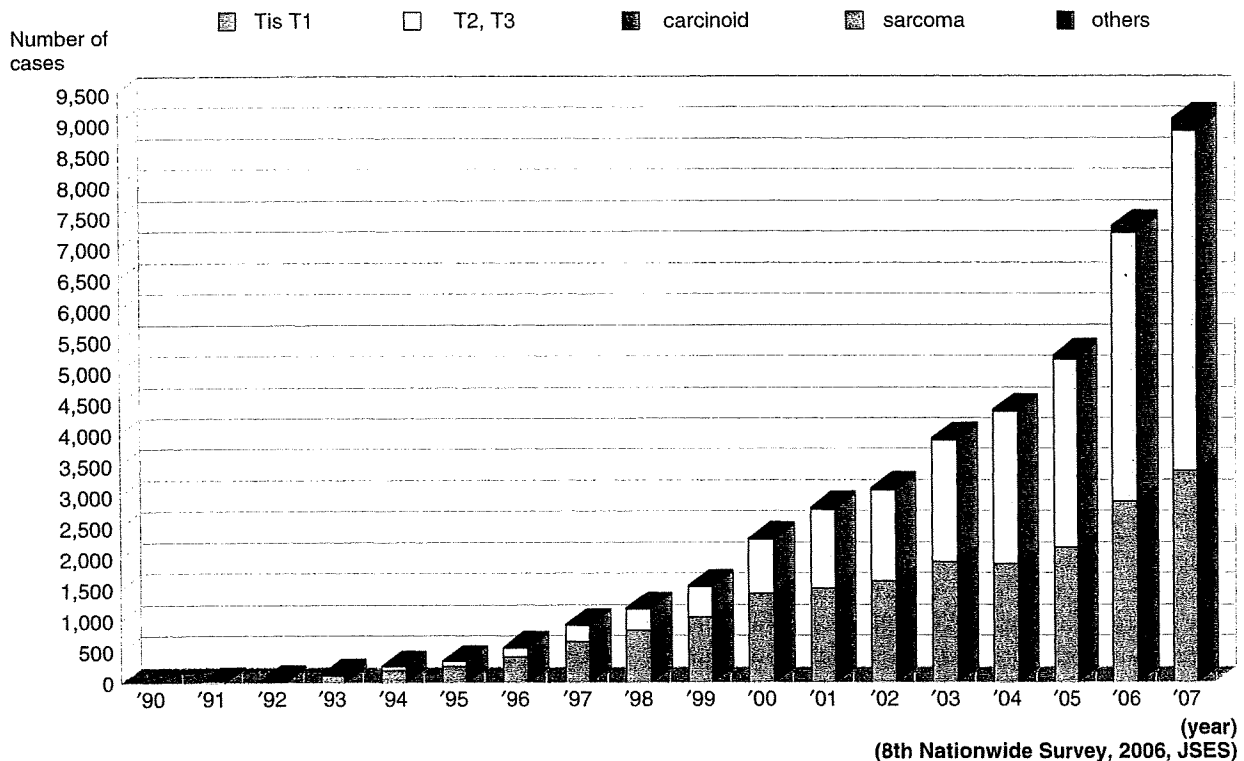
A multicentric phase II study on the feasibility and long-term outcome for stage I and II rectal cancer started in 2008. In this study, the short-term outcomes including anastomotic leakage rate and long-term survival, will be clarified. Combined with continuously improved technologies, training techniques and surgical standards, laparoscopic colorectal surgery is steadily progressing in Japan.

**Introduction**

Laparoscopic surgery has been performed for various diseases of the digestive organs. The benefits of laparoscopic surgery include a reduced likelihood of postoperative ileus, shorter hospital stays, decreased postoperative pain and a smaller incision resulting in good cosmesis. In the field of laparoscopic colorectal surgery such benefits have also been reported both in randomized and non-randomized studies (1–3). Laparoscopic cholecystectomy for gallstone diseases became common in the mid-1990s because of the simplicity of the procedure. While laparoscopic surgery has become a standard treatment for

diseases of a benign nature such as gallstone diseases, it has yet to become the established surgery to treat cancer of the digestive organs. However, laparoscopic colectomy for cancer is the most well-developed technique among other laparoscopic procedures for cancer of the digestive organs.

In 1991, Jacobs *et al.* were the first to report their experiences with laparoscopic-assisted colectomy for benign as well as malignant diseases (4). Due to immense improvements in technique since that time, laparoscopic-assisted colectomy (LAC) for colorectal cancer slowly became the treatment of choice both in Japan and overseas. However, these developments in laparoscopic



**Figure 1** Nationwide survey of laparoscopic colectomy cases for malignant tumors. There is a rapidly increasing tendency in the numbers each year. There were over 9000 cases in 2007. The percentage of more advanced stage cancer cases has been increasing due to the technical advancement in lymph node dissection.

surgery for colorectal cancer occurred at a relatively slow pace primarily because it is a difficult technique and the long-term oncological results are uncertain. According to the surgeons who worked on developing this procedure, the curability of colorectal carcinoma treated with LAC is considered to be as good as that treated with open surgery (5–7). Despite this, the long-term results of LAC for cancer in comparison to open surgery are still controversial. Opinions differ due to uncertainties about the adequacy of resection margin and lymph node dissection and due to the possibility of cancer cell dissemination in the peritoneal cavity and/or to the port sites.

### The development of laparoscopic colorectal cancer surgery in Japan

Laparoscopic colectomy for cancer was first performed in Japan in 1992 – 1 year after Jacobs *et al.* reported on their treatment of benign disease with LAC in the USA. The initial cases were reported by Watanabe *et al.* (8). Initially, LAC was considered as an intermediate procedure between colonoscopic resection and open bowel resection. Although a laparoscopic simple segmental resection for

early stage cancer was considered feasible, it was not known whether an adequate extent of lymph node dissection for more advanced cases could be done in laparoscopic procedures (9). According to the national survey conducted by the Japanese Society of Endoscopic Surgery (committee chaired by Seigo Kitano), the number of cases that undergoing this procedure has steadily increased since it was first introduced, and there were over 9000 cases per year by 2007 (Figure 1) (10). During the early part of the 4 year study (which was conducted between 1994 and 1997), early cancers (Tis and T1) constituted 85%–100% of all the cases. However, during the later part of the study, the percentage of more advanced cancer (T2 or higher) increased to 50%. The increase in the percentage of more advanced cases was due to technical improvements in lymph node dissection (D2, D3 dissection).

For colorectal cancer surgery, three grades of lymph node dissection have been practiced in Japan according to the preoperative and/or intraoperative T staging of the tumor. Provided curative resection is to be performed, D1 dissection is suited for Tis and some T1 stage tumors, D2 dissection is suited for T2 stage tumors, and D3 dissection



**Figure 2** Three grades of lymph node dissection that are practiced in Japanese colorectal cancer surgery. An appropriate grade of dissection is selected according to the preoperative or intraoperative T staging.

is suited for T3 and T4 tumors. The differences in these three grades of lymph node dissection are presented in Figure 2 (11). Konishi *et al.* first reported laparoscopic D3 dissection in both right-sided and sigmoid colon cancer cases, and have shown that the laparoscopic dissection of lymph nodes around the origins of the mesenteric artery branches, such as ileocolic artery or inferior mesenteric artery, is technically feasible and safe (12).

In 1998, the Japanese Society for Cancer of the Colon and Rectum started a working group, the Clinical Research Group of Laparoscopic Colectomy (CRGLC) (chaired by Fumio Konishi; succeeded by Masahiko Watanabe), in order to establish a laparoscopic surgical technique to treat colorectal cancer (13). The clinical research group developed a standardized technique, organized regular training courses in Japan using pigs, and also worked on the retrospective multicentric data analyses of the laparoscopic colectomy cases for colorectal cancer. A standardized technique for both right-sided and left-sided (mainly sigmoid) colon resection for cancer was established by meticulously reviewing videos of study group participants over the course of 4 years (1998–2001). The details of the technique were published in a book entitled *Laparoscopic Colectomy – Approach and Standard Technique* (14). Training courses on laparoscopic colectomy using pigs organized by CRGLC have been held three to four times a year since. It is 1 day course consisting of lectures and hands-on pig surgery. There are approximately 30 participants each time. The details of the training courses held from 1998 to 2001 were reported by Yamada *et al.* in 2002 (15). The multicenter data analysis by the CRGLC covered 1784 cases that were operated on between 1993 and 2000, of which 1692 had sufficient data to be analyzed for long-term outcome. The number of cases in stage II and III was 492 in this series. The 5 year overall survival rate of curatively operated

cases was 98.9% for Stage 0, 98.5% for Stage I, 94.5% for Stage II, 85.9% for Stage IIIa, and 74.6% for Stage IIIb (16). The percentage of port-site recurrence was 0.03%. These retrospectively analyzed data were encouraging but not entirely dependable due to the selection bias in the data collection.

#### Randomized controlled trials – Japanese Trial: JCOG 0404

Although non-randomized comparisons between laparoscopic and open surgery in Japan were favorable towards laparoscopic colectomy with regard to the long-term outcome of colorectal cancer surgery (5,6), there was only one small-scale randomized study (17). On the other hand, in other countries there have been several randomized controlled trials (RCT) comparing laparoscopic surgery to conventional colectomy for colorectal cancers (Table 1). The first reported RCT was a trial in Spain and involved a single institution. The results showed that there was no difference between the two procedures in stage II cases, and that LAC was associated with a significantly reduced risk of tumor relapse and death from cancer in stage III cases (18). In 2008, a long-term follow-up of the same trial showed better survival rates in the laparoscopic groups (19). A National Cancer Institute-sponsored trial in the USA [Clinical Outcomes of Surgical Therapy (COST)] found that there were no differences in the survival rate between laparoscopic and open surgery for both stage II and III colon cancer (20,21). A Colon Cancer Laparoscopic or Open Resection (COLOR) trial in northern Europe was closed for accrual, but the long-term results have yet to be reported (22). A Conventional versus Laparoscopic-Assisted Surgery in Colorectal Cancer (CLASICC) study in the UK reported that there were no differences between laparoscopic and open surgery on both the colon and the rectum (23). Furthermore, a meta-analysis that included COST, COLOR and CLASICC cases, covering a total of 1536 cases, again showed that there were no differences in the long-term outcome between laparoscopic and open surgery (24). Regarding RCT for colon cancer in Asian countries, a small-scale RCT was reported from Taiwan, and the results were similar to those from Western countries (25). While the results of those RCT were encouraging, we still need to have the results of our own RCT in Japan.

Because of the CRGLC's efforts, group members became highly adept at performing laparoscopic colectomies and by the early 2000s a uniform standard was achieved. Despite this, the rate of conversion from open surgery to laparoscopic colectomy in Japanese institutions is generally much lower than that in the previously done RCT in other parts of the world. In 2004, we felt that it was the

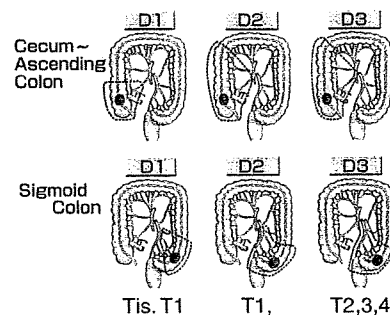


**Table 1** Randomized trials of laparoscopic vs open surgery for long-term results

	COST 2007 Lap vs Open	CLASICC 2007 Lap vs Open *	Liang <i>et al.</i> 2007(6) Lap vs Open	Lacy <i>et al.</i> 2008(7) Lap vs Open
n	435:428	273:140	135:134	106:102
Year	1994–2001	1996–2002	2000–2004	1993–1998
Age	70:69	69:69	64:64	68:71
Exclusion	TNM: T4 and M1, transverse colon	TNM: M1 transverse colon	TNM: T4, right and proximal transverse colon, AJCC Stage I and IV	TNM: T4 and M1, transverse colon
AJCC stage				
I	35%:26%	16.7%:16.4%	0:0	25.4%:17.6%
II	31%:34%	34.6%:36.9%	50.4%:47.8%	39.6%:47.1%
III	26%:28%	36.1%:34.7%	49.6%:52.8%	34.9%:35.3%
IV	4%:2%	Not reported	0:0	4.7%:5.9%
Conversion	21%	25%	3%	11%
Median follow-up	7 years	36.8 months	40 months	95 months
Cancer outcomes				
Overall recurrence	19.4%:21.8%	—	17.0%:21.6%	18%:28%
Cancer related mortality	11.0%:14.3% (2004 data)	22.7%:19.3%	—	16%:27%
Overall mortality	23.6%:25.4%	28.8%:32.2%	—	36%:49%

AJCC, American Joint Committee on Cancer; CLASICC, Conventional versus Laparoscopic-Assisted Surgery in Colorectal Cancer; COLOR, Colon Cancer Laparoscopic or Open Resection; COST, Clinical Outcomes of Surgical Therapy; TNN, tumor metastasis (lymph) node.

right time to start RCT in Japan, and we began to design the RCT comparing laparoscopic versus open surgery. The study was designed by laparoscopic colorectal surgeons from over 20 institutions (members of CRGLC), in collaboration with the Japanese Clinical Oncology Group (JCOG), an organization of the National Cancer Center, Japan. The Japanese Ministry of Health Welfare and Labor funded the study. The study's aim was to enroll 842 cases in 2–3 years, and it sought to prove that the survival rate of LAC is not lower than open colectomy by 7.5% for T3 and T4 tumors. This was a non-inferiority trial in which we intended to prove that the long-term outcome of the two kinds of treatment was equal (26). The inclusion criteria were as follows: (1) patients aged 25–75; (2) patients without associated malignancies; (3) tumors in the cecum, ascending colon, sigmoid colon or in the recto-sigmoid; (4) tumors preoperatively staged as T3 or T4 by preoperative examinations; (5) tumors measuring < 8 cm on preoperative examinations; and (6) tumors that are not causing bowel obstruction. In all cases, D3 lymph node dissection was a required procedure (Figure 3). The Japanese trial started in November 2004 and completed in 2009. Because the interim short-term survival rate was higher than expected by 2007, the number of case accruals was increased to 1050 in order to have a sufficient number for statistical analysis. The case accrual went smoothly and finished in April 2009, with a final enrollment of over 1050 cases. The short-term outcomes will be analyzed in the near future, and we continue to wait for the long-term outcome results.



**Figure 3** A case of upper rectal cancer in which D3 lymph node dissection was done. The lymph nodes around the origin of the inferior mesenteric artery were dissected.

### Qualification system of laparoscopic surgical skill in Japan

Laparoscopic colorectal cancer surgery is one of the more difficult procedures in laparoscopic surgery. It has been 17 years since laparoscopic colorectal surgery was introduced in Japan in 1992. Technical difficulties, including the limited number of training institutions and the difficulty surgeons have in mastering the technique, are still the reasons for the limited usage of the laparoscopic technique for colorectal surgery.

Training involves a variety of teaching methods to ensure that surgeons master laparoscopic technique. Firstly, teaching courses with animal laboratory surgery are useful ways to learn the technique. Virtual training

devices are also useful, but the availability of such devices is limited. Additionally, visiting and observing clinical cases of laparoscopic colorectal surgery in institutions is very helpful before starting and also during the learning period. Thirdly, hands-on learning with experienced surgeons is the most significant form of training. In our experience, a trainee can become independent to carry out standard uncomplicated laparoscopic colorectal surgery after having operated on at least 20 cases under the guidance of an experienced trainer. During the initial period of hands-on learning, stepwise progress in instruction – beginning with the simpler aspects of the procedure and building to the more complex – is often most effective. Throughout training, it is also extremely important to have a good team of laparoscopic colorectal surgeons overseeing and guiding the process to good progress and successful results.

In 2004, the Japan Society of Endoscopic Surgery (JSES) established the Endoscopic Surgical Skill Qualification System (ESSQS) (chaired by Dr Taizo Kimura) for the purpose of encouraging high-level techniques and safe endoscopic surgical procedures. Those who succeed in getting the qualification have both the ability to safely perform endoscopic operations independently and to teach trainees. This is the first technical credential system in the world for laparoscopic surgery. Assessment is conducted by reviewing unedited videos of the applicants performing laparoscopic surgery in one of the sub-classified fields such as biliary tract, esophagus, stomach and colon. Applicants are then assessed on a scale of 100, with 60 marks allocated to "Common Criteria" to evaluate basic endoscopic surgical techniques and 40 marks for "Organ-specific Criteria" to evaluate special surgical techniques. Each applicant has participated either in at least 45 laparoscopic cholecystectomies in addition to five other higher-grade procedures, or in at least 20 or more advanced procedures such as laparoscopic colectomies. Two assessors carefully review identical unedited videos submitted by the applicants. During the first 3 years of ESSQS, there were changes to the types of laparoscopic colorectal surgery approved for video submission as well as changes in the assessment criteria. Due these changes and the higher level of standards, the equitable judgment of the technique became possible (12). As a result, the success rate in the field of colorectal laparoscopic surgery ranged from 37% to 40% (2004–2008) without significant variability. The relatively low success rate is considered adequate because the purpose of the ESSQS is to accredit the technique level with which one can conduct a safe and sufficient operation as well as teach trainees. Kappa Values of Inter-rater Agreement ranged from 0.38 to 0.40 (2004–2008), which can be considered as acceptable to fair. The preoperative complication rate was

significantly lower for successful surgeons than for unsuccessful ones.

The ESSQS continues to be the assessment body for endoscopic surgeons in Japan. It contributes to the establishment of standard technical skills in laparoscopic surgery, the development of educational system and the reduction in complications.

### **Cost problems of laparoscopic colorectal cancer surgery**

Although laparoscopic colorectal surgery is considered beneficial for patients because of its minimal invasiveness, it does create financial problems due to the need for disposable instruments and longer operation time. Changes in reimbursement rates by Japanese public health insurance in 2008 increased the reimbursement rate for laparoscopic colectomy for cancer rose by 90,000 yen (approximately US\$937), or to 417,000 yen (US\$4344) per operation. Similarly, reimbursement for laparoscopic rectal resection for cancer rose by 92,000 yen (US\$958), to 534,000 yen (US\$5562) per operation. In addition to these reimbursements, public health insurance pays 30,000 yen (US\$312) for the cost of laparoscopic coagulating shears and up to 100,000 yen (US\$1041) for stapling devices. However, the reimbursements for these disposable instruments are insufficient because hospitals pay more than these amounts to suppliers. Additionally, insurance does not cover certain other disposable instruments, such as trocars and clips. Under the Japanese public health insurance system, hospitals are not allowed to claim for the extra costs related the instruments. Likewise, the extra cost for the longer operation is not paid for by the insurance, and the shorter hospital stay for laparoscopic colectomy patients is not enough to compensate for the excess spending. Therefore, under the Japanese public health care system, hospitals may lose money if surgeons perform laparoscopic colorectal cancer surgeries. To solve such problems, we should make strenuous negotiations with the Ministry of Health and Labor to raise the reimbursement rates. On the other hand, surgeons should consider decreasing the number of disposable instruments used in the operations, which can be replaced by reusable instruments.

### **Future directions of laparoscopic colorectal surgery in Japan**

Laparoscopic rectal cancer surgery is not as simple as laparoscopic colectomy because of its anatomical complexities. Particularly, the dissection and the division of the rectum in the deep part of the pelvic cavity sometimes involve complications. In addition to complications, the lateral pelvic node dissection for T3, T4 lower rectum tumors is

**Table 2** Randomized trials comparing laparoscopic and open surgery for rectosigmoid and rectal tumors

	Leung <i>et al.</i> 2004(1) Rectosigmoid Lap vs Open	CLASICC 2007 Lap vs Open	Zhou <i>et al.</i> 2004 (26) Lap vs Open
n	203:200	253:128	82:89
Year	1993–2002	1996–2002	2001–2002
Age	67:67	69:69	44:45
TME	NA	79%:67%	100%
Site in rectum	NA	Not reported	1.5–8 cm from dentate line
AJCC stage			
I	15.3%:14.0%	16.7%:16.4%	6.1%:6.7%
II	35.5%:36.5%	34.6%:36.9%	11.2%:9.0%
III	31.5%:34.5%	36.1%:34.7%	76.8%:76.4%
IV	17.7%:15.0%	Not reported	4.9%:8.5%
Conversion	23.2%	34%	Not reported
30 day mortality	0.6%:2.4%	4%:5%	0%:0%
Median follow-up	52.7 months	36.8 months	Range 1–16 months
Cancer Outcomes			
Locoregional recurrence	6.6%:4.1%	9.9%:9.4%	0%:3.4%
Distant recurrence	18.0%:15.3%	18.6%:16.4%	0%:0%
Cancer related mortality	15.6%:11.8%	12.6%:18.0%	0%:0%
Overall mortality	22.8%:23.5%	Not specifically reported	0%:0%

AJCC, American Joint Committee on Cancer; CLASICC, Conventional versus Laparoscopic-Assisted Surgery in Colorectal Cancer; TME, total mesorectal excision.

technically challenging if it is to be performed laparoscopically. At the moment, laparoscopic lateral node dissection is still in the experimental stage and conducting a trial on laparoscopic resection of advanced low rectal cancers remains extremely difficult in Japan.

Globally, there have been few good quality studies comparing laparoscopic surgery to open surgery for rectal cancers. There are only three randomized studies available in the world (Table 2) (3,23,27). Of these trials, the study from Hong Kong is only on rectosigmoid lesions, and the results were similar to colon cancer surgery. Of the other trials on rectal cancer, the CLASICC trial is the only one that presented dependable results, but there was a relatively high conversion and morbidity rate in this study (23). In the study by Zhou *et al.* (27), the methodology of the study was unclear and the follow-up period was very short. Therefore, long-term outcomes of laparoscopic rectal cancer surgery as compared to open surgery remain unclear. In the future, COLOR II and LAPKON II trials may provide good information regarding the long-term outcome of laparoscopic rectal cancer surgery compared to open surgery.

In Japan, retrospective multicentric data collection and the analysis of laparoscopic rectal cancer surgery were done by the Japan Society of Laparoscopic Colorectal Surgery (previously named the CRGLC). The results of this study were reported by Miyajima *et al.* (28). Of the 1011 curatively treated patients in their series, the 3 year disease-free survival rate was 100% in stage 0, 94.6% in stage I, 82.1% in stage II, and 79.7% in stage III. These rates were similar to the results of open surgery. A phase II prospective, non-randomized trial on the feasibility of laparoscopic rectal resections for early stage rectal cancers is currently being conducted under the direction of the Japan Society of Laparoscopic Colorectal Surgery. The sample size is 350. The short-term outcome is mainly focused on the anastomotic leakage rate while the long-term measure is disease-free survival (29).

## Conclusions

Laparoscopic colorectal cancer surgery in Japan developed more or less in parallel to Western and other Asian countries. However, in Japan, similar to open colorectal cancer surgery, lymph node dissection has been meticulously done in laparoscopic surgery. The high-level technique of laparoscopic D3 dissection is a special skill in our practice. Our randomized controlled trial started after the technique was established. Considering the very low conversion to open rate in Japan, our multi-centric prospective trials may produce new results that are different from those in Western and other Asian countries.

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