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ORIGINAL ARTICLE

Randomized controlled trial to evaluate laparoscopic versus open surgery in transverse and descending colon cancer patients

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Abstract

Background The safety and efficacy of laparoscopic surgery for transverse and descending colon cancer remain controversial. This study aimed to evaluate the short- and long-term outcomes of this procedure.

Methods We conducted a single-institutional randomized controlled trial. Patients with transverse or descending colon cancer were randomly allocated to receive laparoscopic surgery (LAC) or conventional open surgery (OC). The primary endpoint was the overall complication rate between the two groups. The secondary endpoints were the length of the postoperative hospital stay, the health-related quality of life (HRQOL) score (at 1, 6, and 12 months after surgery), the 5-year relapse-free survival (RFS), and the 5-year overall survival (OS).

Results Between August 2008 and October 2012, a total of 66 patients were enrolled (33 in the LAC group and 33 in the OC group). The patient characteristics showed no significant differences between the two groups. The complication rates (≥ grade 3) were 6.1% in the LAC group and 12.1% in the OC group ($p = 0.392$). The length of postoperative stay was not significantly different between the two groups. Regarding the HRQOL, the physical functioning, role physical, bodily pain, social functioning, mental health, and role component summary at 1 month after surgery and the social functioning and mental health at 6 months after surgery were better in the LAC group than in the OC group. The 5-year RFS and OS rates were similar between the LAC and OC groups (RFS 90.5% and 87.3%, respectively, $p = 0.752$; OS 93.3% and 100.0%, respectively, $p = 0.543$).

Conclusions The short- and long-term outcomes of laparoscopic surgery for transverse and descending colon cancer are almost equal to those of open surgery. Laparoscopic resection is a better choice than open surgery for managing this cancer with regard to the short- and mid-term QOL.

Trial registration ClinicalTrials.gov Identifier: NCT01861691.

Keywords Laparoscopic surgery · Descending colon cancer · Transverse colon cancer · Randomized clinical trial · Quality of life · Colon cancer

Introduction

The long-term results of several large-scale prospective randomized trials that compared laparoscopic and open colectomy for colon cancer have been published over the past decade [1–4]. The oncologic outcomes were similar between patients who underwent laparoscopic and open surgery. Therefore, laparoscopic surgery for colon cancer has become recognized as an alternative for open surgery. In Japan, the Japan Clinical Oncology Group (JCOG) conducted a randomized trial to compare the oncological outcomes between patients who underwent laparoscopic and open surgery for advanced colon cancer and recto-sigmoid cancer [5]. However, the exclusion criterion concerned tumor sites in the transverse and descending colon. Distal transverse colon cancer is difficult in lymph node dissection because there are important structures around middle colic artery and vein, such as the pancreas, duodenum, and superior mesenteric vein, and dissection in the wrong plane may cause serious complications.

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Descending cancer has the lymphoid system draining to superior mesenteric artery and the inferior mesenteric artery, and so, problems are that the lack of standardized lymph node dissection and technical difficulties pertinent to splenic flexure dissection essential to providing sufficient resection margins [6, 7]. Recently, Watanabe et al. reported the diversity of lymph flow in splenic flexural colon cancers using laparoscopic real-time indocyanine green fluorescence imaging [6, 7]. It is difficult to perform lymph node dissection at this site laparoscopically. In addition, the incidences of transverse colon cancer and descending cancer are low. Therefore, patients with tumors in these locations have typically been excluded from randomized controlled trials.

Several recent studies have described the feasibility and safety of laparoscopic surgery for transverse and descending colon cancer [8–12]. There are few reports that describe the long-term outcomes of this surgery. Previous retrospective studies have reported that laparoscopic transverse colectomy showed better short-term results than open surgery with acceptable oncologic outcomes [13–15]. However, no randomized controlled trial has been reported.

It is well accepted that laparoscopic surgery offers a quicker recovery, less pain, and better cosmesis than open surgery. However, whether or not the postoperative recovery after laparoscopic surgery provides a beneficial health-related quality of life (HRQOL) remains controversial. Theodoropoulos et al. reviewed 20 studies that used various HRQOL tools to assess the QOL after laparoscopic colectomy for cancer [16]. They reported that long-term beneficial effects on the patient HRQOL of laparoscopic colectomy for cancer compared with open resection have not been clearly shown. Aside from a few studies, longitudinal assessments of HRQOL have not been widely available. Furthermore, there are no reports that describe the longitudinal assessment of the HRQOL after laparoscopic colectomy for transverse and descending colon cancer compared with open surgery.

We therefore conducted a randomized trial that compared laparoscopic surgery and conventional open surgery in transverse and descending colon cancer. The purpose of the present study was to clarify the safety and feasibility of laparoscopic surgery on transverse and descending colon cancer patients. In addition, we assessed the longitudinal HRQOL of laparoscopic surgery compared with open surgery.

Methods

Patients

This was a randomized controlled trial conducted at a single institute. The study protocol was approved by the Ethical Advisory Committee of Yokohama City University School of Medicine before the study was initiated. The trial was registered with ClinicalTrials.gov: NCT01861691. Between August 2008 and October 2012, 66 patients who had transverse or descending colon cancer were enrolled in this study and randomly allocated to receive laparoscopic surgery (LAC) or open surgery (OC). The inclusion criteria were an age of ≥ 20 years, histologically proven adenocarcinoma, no bulky tumor (> 8 cm in diameter), no metastasis, elective operation, tolerable surgery under general anesthesia, no history of laparotomy for colorectal resection except appendectomy, and written informed consent provided. The diagnosis was to be made by barium enema or colonoscopy. Metastatic disease was excluded by radiological imaging of the chest and liver. The exclusion criteria were as follows: synchronous or metachronous (within 5 years) malignancy in another organ except for carcinoma in situ, multiple colorectal cancer requiring reconstruction two or more times, acute intestinal obstruction or perforation due to colorectal cancer, and pregnant or lactating women.

Randomization and masking

Randomization and data handling were performed by the Department of Gastroenterological Center Data Center of Yokohama City University. After confirming the inclusion/exclusion criteria and obtaining written informed consent, patients were randomized by computerized randomization following a fax to the data center on the morning of surgery. The allocated procedure was not concealed from investigators or patients. The sizes of the groups were balanced using the minimization method according to the tumor location (transverse colon, descending colon).

Surgical procedures

All surgical procedures were performed by one specialized colorectal treatment team. The laparoscopic surgeries were performed by a surgeon who passed the skill accreditation system for laparoscopic gastroenterological surgery, established by the Japanese Society for Endoscopic Surgery (JSES), and all open surgeries were performed under the supervision of these skilled 3 surgeons which include the laparoscopic surgeon. In both arms, complete mesocolic excision (CME) with central vascular ligation (CVL) was performed. In CME with CVL for splenic flexure colon cancer, the left branch of the middle colic artery and left colic artery should be ligated at their origin. In CME with CVL for descending colon cancer, the left colic artery should be ligated at its origin. The left branch of the middle colic artery should be ligated at their origin if the artery is within 10 cm proximal to the tumor. The inferior mesenteric vein was ligated at the inferior border of the pancreas for both locations. Left accessory aberrant colic artery should be ligated at its origin for both locations if it presented. The laparoscopic procedure was performed using

5 ports: a 12-mm port in the umbilical region, 5-mm ports in the upper right, left and lower right, left quadrants. A 12-mm umbilical trocar was used as a camera port for a rigid scope. Conversion to open surgery was defined as unplanned skin incision (wounds ≥ 8 cm in length) for the control of intraoperative complication, severe adhesion, or unexpected tumor extension. CVL and colon mobilization were performed laparoscopically. The specimen was extracted through the umbilical port, which was extended to approximately 2–5 cm. To avoid contamination, a wound protector was used in each patient. Anastomosis was performed with a functional end-to-end anastomosis using the Endo GIA™ Universal (Medtronic, MN, USA) or Echelon™ 60 (Ethicon Endo-Surgery, OH, USA) stapler extracorporeally. For conventional open surgery, the patients were placed in the supine position and a midline skin incision (wounds ≥ 8 cm in length) was performed. The anastomosis techniques were the same as those used in laparoscopic surgery.

Adjuvant therapy and follow-up

The pathological stage of transverse and descending colon cancer was based on the seventh edition of TNM classification of colorectal cancer, which was proposed by the International Union against Cancer (UICC) and American Joint Committee on Cancer (AJCC) [17].

When the pathological stage was diagnosed as stage III by a histological examination of the resected specimen, adjuvant chemotherapy was performed with oral fluoropyrimidine anticancer drug for 6 months. Neither radiation therapy nor preoperative chemotherapy was given to any patient.

The follow-up schedule was as follows according to the stage: patients with stages 0 and I were followed up with outpatient examinations, including tumor marker measurements, and chest, abdominal, and pelvic computed tomography (CT) once a year for 5 years; patients with stage II and IIIA were examined by CT and underwent tumor marker measurements every 6 months for the first 2 years, with these examinations performed once a year from the third to the fifth year; and patients with stage IIIB and IIIC were examined by CT and underwent tumor marker measurements every 4 months for the first 2 years and every 6 months from the third to the fifth year.

Outcomes

The primary endpoint was the complication rate (≥ grade 3) within 30 days. The secondary endpoints were the length of the postoperative hospital stay, the HRQOL score, the five-year relapse-free survival (RFS), and the five-year overall survival (OS). The terminologies of the complications were classified according to the Common Terminology Criteria for Adverse Events (CTCAE) version 4.03, and grading was done based on the Classification of Surgical Complications [18].

The HRQOL score was measured using the 36-item Short Form Health Survey (SF-36) version 2.0, which was based on the Japanese National Reference [19]; this is a tool that measures the HRQOL according to an inclusive standard and not a disease-specific standard. A genetic instrument was believed to be better suited to this trial than a disease-specific instrument because the assessment involved a wide range of disease processes. The SF-36 is composed of 36 questions. The score is expressed numerically by the provided scoring algorithm. Eight different health-related quality items composed of the physical function (PF), role physical (RP), bodily pain (BP), general health (GH), vitality (VT), social functioning (SF), role emotional (RE), and mental health (MH) were compared in both groups. The Physical and Mental Component Summaries (PCS, MCS) that are calculated from these eight items were then compared.

SF-36 questionnaires were sent to the patients 1, 6, and 12 months after the surgery by postal mail. A return envelope was enclosed with the SF-36 questionnaire, and the patient sent it back to the research secretariat by postal mail.

Statistical analyses

A power analysis determined that 37 patients would be required to demonstrate a reduction in the incidence of postoperative complications within 30 days by LAC instead of OC from 40 to 20% at a significance level of 5% and power of 80%. A reduction in the incidence of postoperative complications is according to the previous similar study [20].

The statistical analysis was performed with the IBM SPSS software program, version 22 (SPSS Inc., Chicago, IL, USA). The continuous variables were compared between the groups using Student's t test. Pearson's chi-squared test was used to compare discrete variables. Survival curves were produced using the Kaplan-Meier method. Statistically significant differences between the groups were determined by the log-rank test. A p value < 0.05 was considered statistically significant.

Results

Between August 2008 and October 2012, a total of 66 patients were enrolled. Thirty-three patients underwent LAC, and 33 patients underwent OC (Fig. 1). The median follow-up of all patients was 71 months. The baseline factors were well balanced between the arms (Table 1). The surgical procedure and outcomes are summarized in Table 2. The duration of operation in the LAC group was significantly longer than that in the OC group (179 vs. 140 min, $p = 0.010$). The blood loss in the LAC group was significantly less than that in the OC group (30 vs. 100 ml, $p = 0.001$). The complication rate (≥ grade 3)

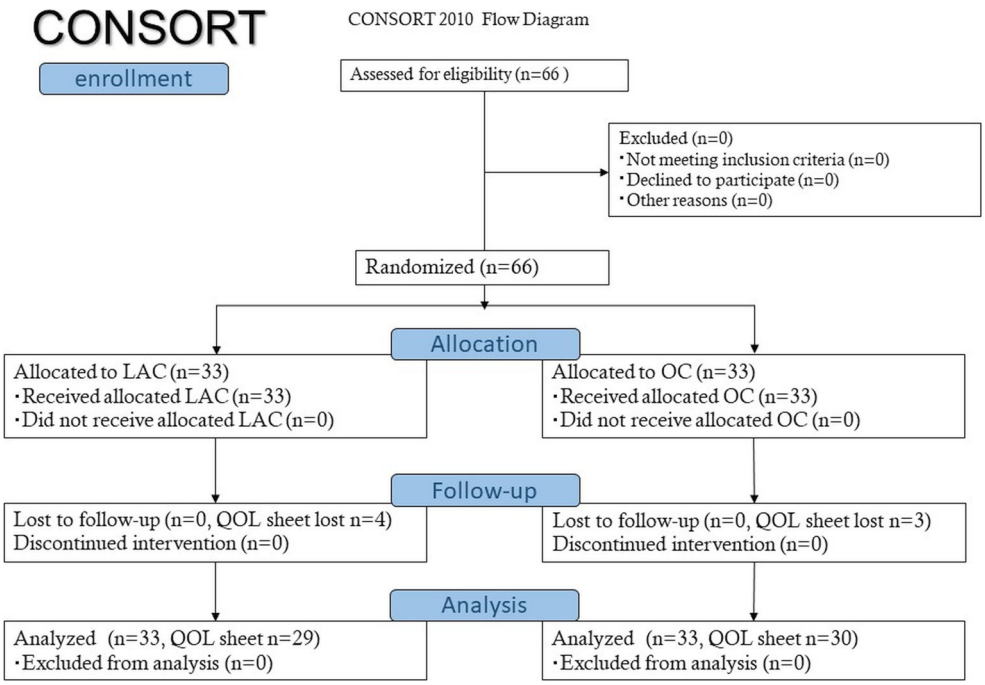

Fig. 1 Trial schema. LAC laparoscopic surgery, OC open surgery

was 6.2% in the LAC group and 12.1% in the OC group ($p = 0.392$), and the median length of postoperative hospital stay was 8 days in both groups ($p = 0.625$). Intra-abdominal abscess unrelated to anastomotic leakage occurred in 1 case in the LAC group and 1 case in the OC group. One case who underwent laparoscopic transverse colectomy was treated by CT-guided drainage. Another case who underwent descending colectomy was treated by re-operation. Wound infection occurred in 1 patient in the LAC group and 3 patients in the OC group. All wound infection was grade 2. Small bowel obstruction (SBO) occurred in 1 patient in the OC group. Patient with SBO was treated by long tube drainage. There were two anastomotic leakages in the OC group. Two cases were treated by CT-guided drainage. Pancreatic fistula occurred in 1 patient in the LAC group. This patient was treated by CT-guided drainage and a low-fat diet. The pathologic outcome did not differ significantly between the two groups (Table 3).

Table. 1 Patients characteristics

	LAC ($n = 33$)	OC ($n = 33$)	p
Age (years), median (IQR)	64 (57–74)	67 (59–72)	0.378
Gender male/female	24/9	16/17	0.076
Comorbidity			
Hypertension	14	16	0.621
Diabetes mellitus	1	4	0.163
Coronary heart disease	1	3	0.302
ASA score			
I	11	8	0.415
II	22	25	
Body mass index (kg/m^2), median (IQR)	23 (20–26)	23 (21–25)	0.224
Pre-operative serum CEA (ng/ml), median (IQR)	2.0 (1.6–2.8)	3.0 (1.6–3.6)	0.175
Prior abdominal surgery	10	7	0.398
Tumor location			
Transverse	21	21	
Descending	12	12	

LAC laparoscopic surgery, *OC* open surgery, *ASA* American Society of Anesthesiologists classification, *CEA* carcinoembryonic antigen

Table. 2 Surgical procedure and outcomes

	LAC ($n = 33$)	OC ($n = 33$)	p
Surgical procedure			
Right hemicolectomy	5	2	0.775
Transverse colectomy	15	18	
Left hemicolectomy	3	6	
Descending colectomy	9	6	
Operating time (min), median (IQR)	179 (137–195)	142 (132–185)	0.010
Blood loss (ml), median (IQR)	30 (10–50)	100 (50–258)	0.001
Conversion to open surgery, *n* (%)	0 (0)		
Total morbidity (CTCAE ≥ grade 3), *n* (%)	2 (6.1%)	4 (12.1%)	
Intra-abdominal abscess	1	1	0.392
Small bowel obstruction	0	1	
Anastomotic leakage	0	2	
Pancreatic fistula	1	0	
Re-operation	0	1	0.314
Postoperative stay (days), median (IQR)	8 (8–8)	8 (8–14)	0.625
Mortality	0	0	

CTCAE Common Terminology Criteria for Adverse Events version 4.03, *CD* Clavien–Dindo classification

Fifty-nine patients replied to the questionnaire concerning their HRQOL (89.3%). At 1 month after the operation, the LAC group showed a significantly better PF (49.8 ± 8.4 vs. 42.9 ± 10.0; 95% confidence interval [CI] 1.43–12.44; $p = 0.015$), RP (42.8 ± 14.7 vs. 32.7 ± 14.3; 95% CI 1.33–18.91; $p = 0.025$), BP (50.0 ± 7.8 vs. 44.4 ± 9.4; 95% CI 0.37–10.77; $p = 0.036$), SF (46.3 ± 9.7 vs. 37.1 ± 13.7; 95% CI 2.15–16.25; $p = 0.012$), MH (52.3 ± 8.9 vs. 45.5 ± 9.6; 95% CI 1.15–12.42; $p = 0.019$), and RCS (41.4 ± 13.1 vs. 31.3 ± 15.8; 95% CI 1.37–18.96; $p = 0.025$) than the OC group (Fig. 2a). At 6 months after surgery, the LAC group showed a significantly better SF (54.5 ± 6.9 vs. 45.8 ± 12.0; 95% CI 3.02–14.29; $p = 0.003$) and MH (55.8 ± 6.9 vs. 49.3 ± 11.0; 95% CI 1.09–11.96; $p = 0.020$) than the OC group (Fig. 2b). There were no significant differences between the LAC and OC groups at 12 months after surgery (Fig. 2c).

The 5-year RFS rates were 90.5% in the LAC group and 87.3% in the OC group ($p = 0.752$). The 5-year OS rates were 93.3% in the LAC group and 100.0% in the OC group ($p = 0.543$). There were no significant differences between the two groups (Fig. 3a, b).

Table. 3 Pathologic outcomes

	LAC ($n = 33$)	OC ($n = 33$)	p
Tumor size (cm), median (IQR)	2.4 (1.3–3.0)	3.2 (2.0–5.4)	0.159
Distal resection margin (cm), median (IQR)	7.3 (6.8–12.0)	9.2 (5.0–10.0)	0.297
Proximal resection margin (cm), median (IQR)	10.0 (8.0–15.0)	12.5 (7.0–12.7)	0.402
No. of lymph node harvested, *n* median (IQR)	19 (12–32)	25 (18–31)	0.571
Histologic differentiation			
Well (tub1)	18	20	0.293
Moderate (tub2)	9	11	
Poorly (por, sig)	6	2	
Pathological stage (pTMN 7th)			
0	2	0	0.440
I	19	11	
II (A/B/C)	7 (4/3/0)	14 (8/4/2)	
III (A/B/C)	5 (1/2/2)	8 (1/7/0)	
IV	0	0	
Postoperative adjuvant therapy, *n* (%)	8 (24.2)	9 (27.3)	0.778

tub1 well-differentiated tubular adenocarcinoma, *tub2* moderately differentiated tubular adenocarcinoma, *por* poorly differentiated adenocarcinoma, *sig* signet-ring cell carcinoma, *TMN 7th* tumor–node–metastasis classification in UICC 7th

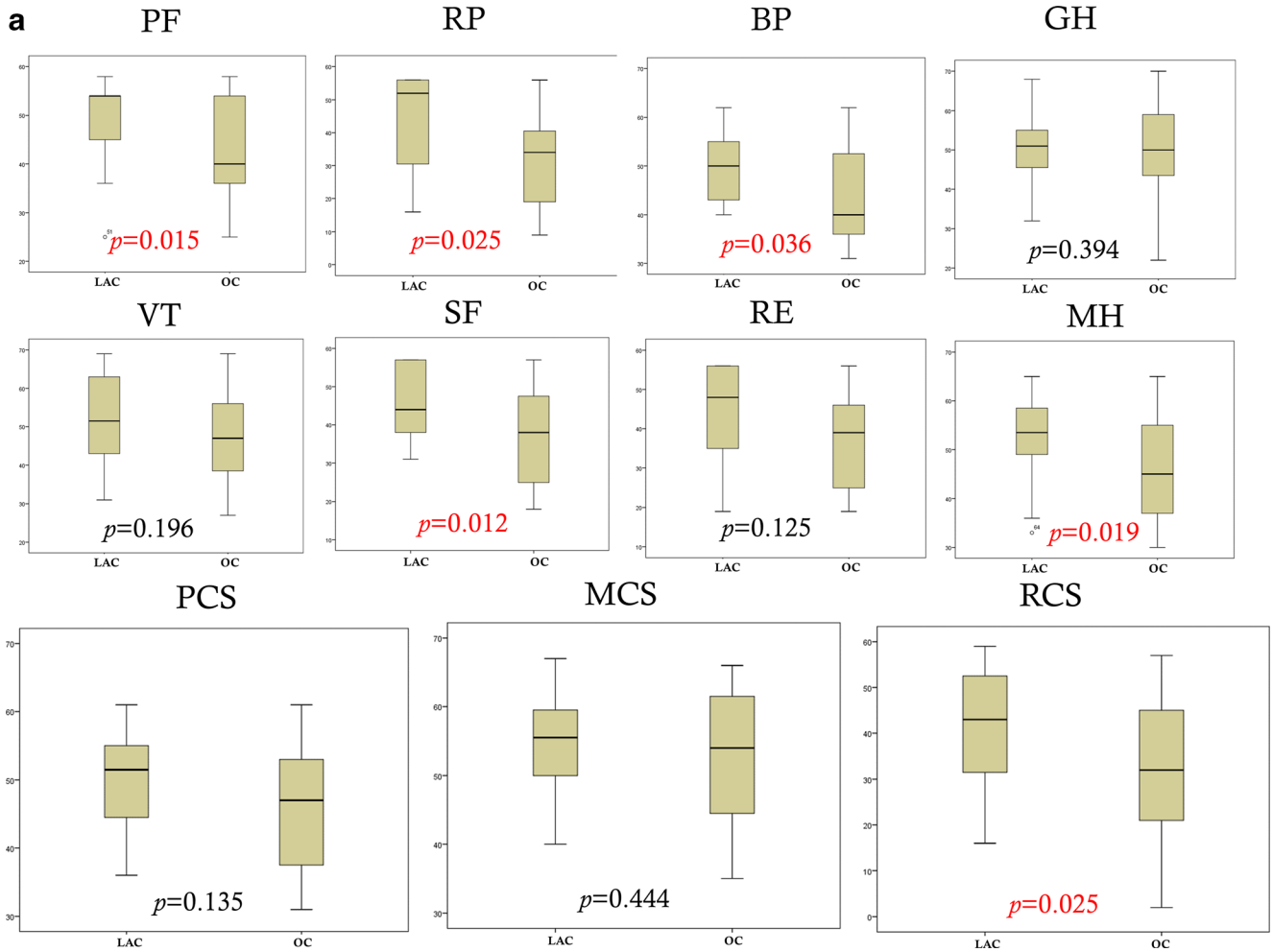

Fig. 2 Health-related quality of life scores **a** 1 month, **b** 6 months, **c** 12 months. PF physical functioning, RP role physical, BP bodily pain, GH general health, VT vitality, SF social functioning, RE role emotional, MH mental health, PCS physical component summary, MCS mental component summary, RCS role component summary

Discussion

We conducted a randomized controlled trial to compare the outcomes of laparoscopic and open surgery in transverse and descending colon cancer patients. A total of 66 patients were enrolled in this trial. This study showed that the short-term outcomes RFS and OS after laparoscopic surgery were almost equal to those with open surgery, and laparoscopic resection appeared to be a better choice than open surgery with regard to the short- and mid-term QOL. To our knowledge, this is the first randomized controlled trial to compare laparoscopic surgery for transverse and descending colon cancer with open surgery and to assess the longitudinal HRQOL as well.

In this study, the primary endpoint was the complication rate (≥ grade 3). The postoperative complication rates were 6.1% in the LAC group and 12.1% in the OC group, showing no significant difference. In the LAC group, postoperative complications occurred in two patients: abdominal infection in one and pancreatic fistula in one. In the OC group, postoperative complications occurred in four patients: abdominal infection in one, ileus in one, and anastomotic leakage in two. In a previous multicenter retrospective study of 1830 patients with transverse and descending colon cancer, the postoperative morbidity rate was significantly higher in the OC group than in the LAC group (25.2% vs. 15.8%) [21]. With regard to the complications, wound infection occurred less frequently in the LAC group than in the OC group (6.4% vs. 9.7%) and no significant difference was noted between the groups in the rate of ileus (open 4.1% vs. laparoscopic 2.6%) and anastomotic leakage (open 0.9% vs. laparoscopic 1.0%). In contrast to the previous study, the postoperative complication rates were not significantly different between the two groups, although the complication rate was lower in our trial than in the previous study, possibly because the laparoscopic surgeries were performed by surgeons who had passed the skill accreditation system for laparoscopic gastroenterological surgery, established by the JSES.

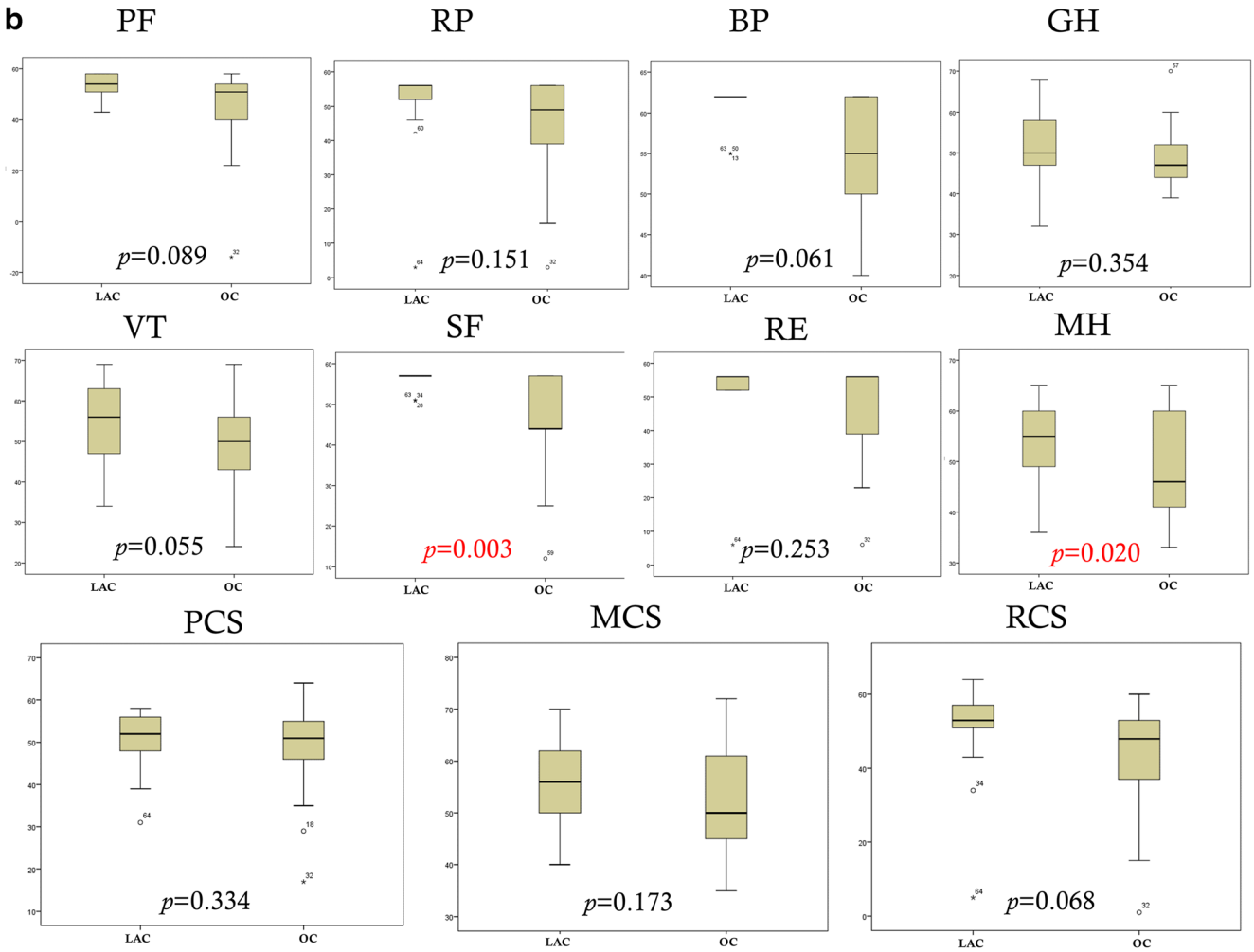

Fig. 2 (continued)

No patients (0%) underwent conversion to open surgery in this trial, which is a lower rate than those observed in the Clinical Outcomes of Surgical Therapy trial (21%) and the Colon Cancer Laparoscopic or Open Resection trial (19%) [4, 22]. However, the surgical techniques and devices have improved since those trials were performed. In retrospective multicenter studies of 1495 cases of colon cancer and 1830 cases of transverse and descending colon cancer in Japan, the rates of conversion to open surgery were 4.8% and 4.5%, respectively [21]. This may be explained by the fact that the BMI of Japanese patients is generally lower than that of patients in Western countries.

One of the secondary endpoints in the present study was the length of the postoperative hospital stay. The median postoperative hospital stay was 8 days in the LAC group and 8 days in the OC group, showing no significant difference. In a systematic review and meta-analysis of 1415 patients with transverse colon cancer who underwent a laparoscopic or open approach, a laparoscopic approach was found to be associated with a shorter hospital stay (weighted mean difference = − 2.94 [− 4.27, − 1.62]; $p = 0.0001$) [23]. Similarly, in a previous multicenter retrospective study of 1830 patients with transverse and descending colon cancer, the median postoperative hospital stay was shorter in the LAC group than in the OC group (12 days in the OC group vs. 10 days in the LAC group; $p < 0.001$) [21]. In contrast to these previous studies, however, the length of the postoperative hospital stay showed no significant difference between the two groups in this trial, possibly due to the fact that the median postoperative hospital stay of the open group in this trial was shorter than in previous studies.

Regarding the HRQOL score (at 1, 6, and 12 months after surgery) assessed using the SF-36 questionnaire, this study showed that the PF, RP, BP, SF, MH, and RCS at 1 month after surgery and the SF and MH at 6 months after surgery were better in the LAC group than in the OC group; however, no significant differences were noted at 12 months after surgery. The SF and MH were high in both groups at 12 months after surgery. Theodoropoulos et al. reviewed 20 studies that used various HRQOL tools to assess the QOL after laparoscopic colectomy for cancer [16]. They reported that long-term beneficial effects on the patient HRQOL of laparoscopic colectomy for cancer compared with open resection have not been clearly shown. Few large-scale multicenter randomized

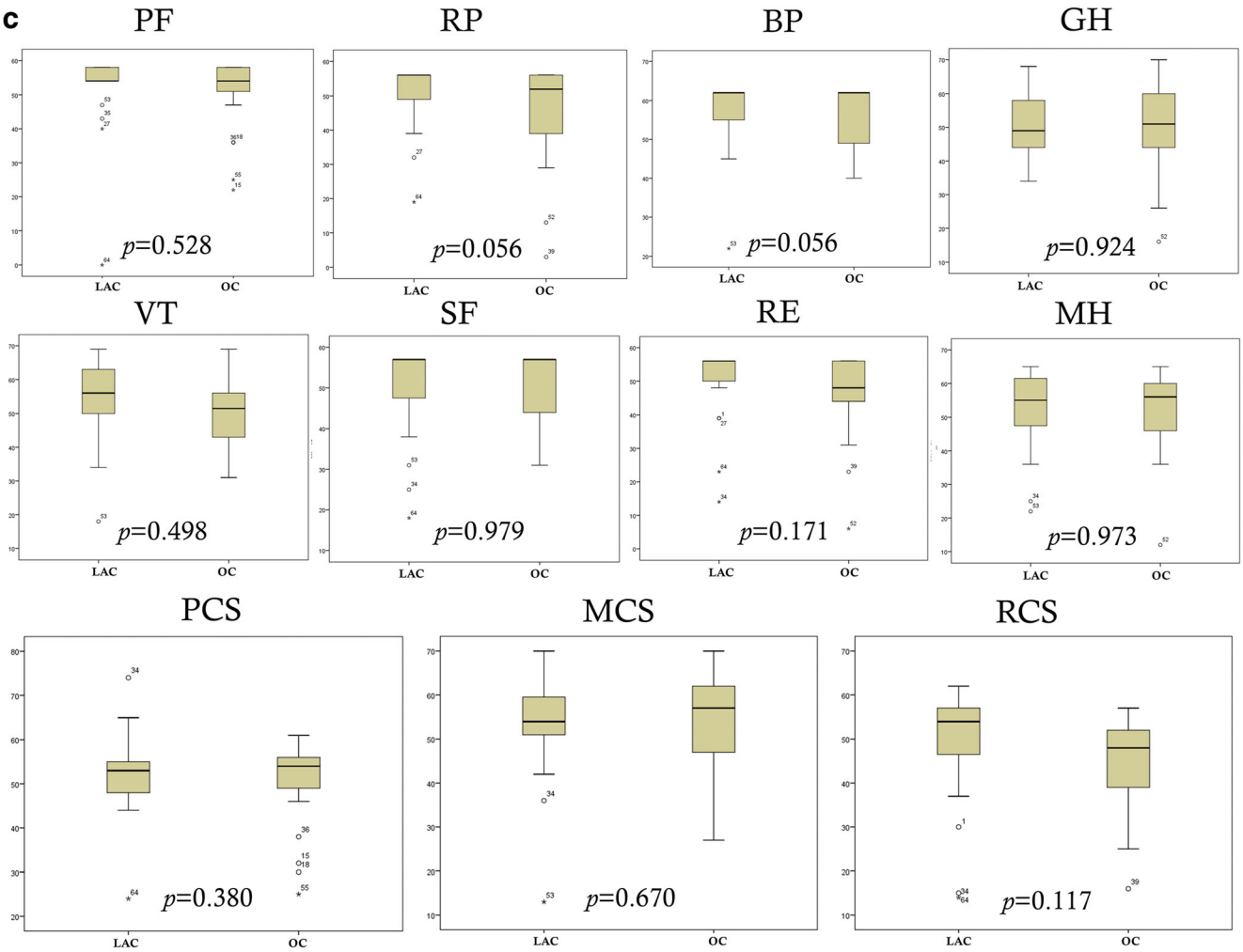

Fig. 2 (continued)

studies have compared the HRQOL after laparoscopic and open resection for colorectal cancer patients [24–26]. The Laparoscopic-Assisted Surgery in Colorectal Cancer trial (CLASCC) Group analyzed the HRQOL in 696 patients at 2 weeks and 3, 18, and 36 months after surgery using the EORTC QOL-C30 [27] and QOL-C30 [28]. They reported no significant differences between the OC and LAC groups [24]. The Clinical Outcomes of Surgical Therapy (COST) Study Group analyzed the HRQOL in 428 patients at 2 days, 2 weeks, and 2 months after surgery, finding that the LAC group reported significantly better physical pain than the OC group at 2 months after surgery [25]. Braga analyzed the HRQOL in 391 patients at 12, 24, and 48 months after surgery using the SF-36 and reported that the GH, PF, and SF at 12 months and the SF at 24 months were better in the LAC group than in the OC group [26]. In another randomized study, the HRQOL at 4 months after surgery in the LAC group was better than in the OC group [29]. Consistent with previous studies, the short- and mid-term HRQOL appeared to be better in the LAC group than in the OC group in the present study but the long-term HRQOL remains controversial.

The 5-year RFS rates were 90.5% in the LAC group and 87.3% in the OC group in our study, showing no significant difference. In previous single-center retrospective studies, laparoscopic transverse colectomy was associated with better short-term results than open surgery with acceptable oncologic outcomes [13–15]. In a previous multicenter retrospective study, 1830 patients with transverse and descending colon cancer who underwent laparoscopic or open R0 resection were registered [21]. The 3-year recurrence-free survival (RFS) rate for stage I was significantly better in the laparoscopic group than in the open resection group (open 92.7% vs. laparoscopic 97.8%, $p = 0.001$), with no statistically significant differences in the 3-year RFS rate for stages II and III (II: open 86.2% vs. laparoscopic 89.4%, $p = 0.21$; III: open 71.4% vs. laparoscopic 77.5%, $p = 0.13$). Why the laparoscopic group showed better results for stage I was unclear. Consistent with previous reports, the present study showed that the RFS after laparoscopic surgery was almost equal to that after open surgery.

This study had several limitations. First, this was a single-institution study, with almost the same procedure conducted in all cases, and the population was small and wholly comprised

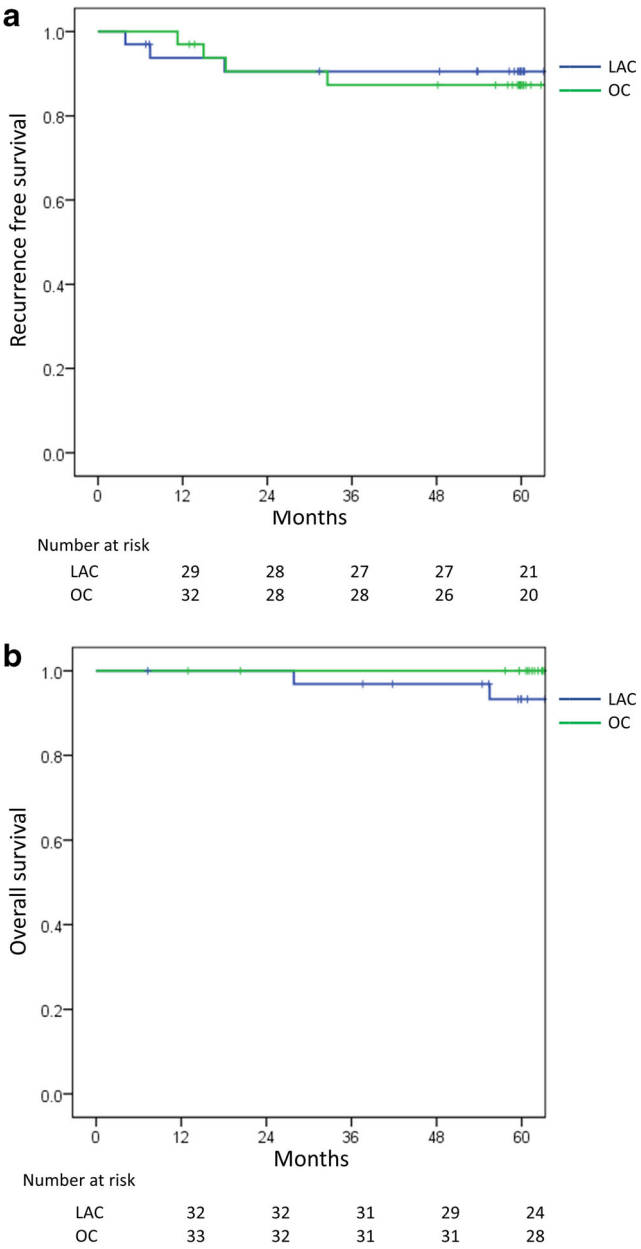

Fig. 3 Oncologic outcome. **a** Recurrence-free survival rates between the two groups. **b** Overall survival rates between the two groups. LAC laparoscopic surgery, OC open surgery

Japanese patients. Second, we scaled back this study to 66 patients after enrolling patients for 4 years. Third, regarding the stage, although there were no significant differences between LAC and OC, more stage III patients were assigned to the OC group.

In conclusion, short- and long-term outcomes of laparoscopic surgery for transverse and descending colon cancer are almost equal to those of open surgery. Laparoscopic resection is a better choice than open surgery for managing this cancer with regard to the short- and mid-term QOL.

Compliance with ethical standards

The study protocol was approved by the Ethical Advisory Committee of Yokohama City University School of Medicine before the study was initiated.

Conflict of interest The authors declare that they have no conflict of interest.

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