SCIENTIFIC PAPER

Evaluations of Laparoscopic Proctocolectomy Versus Traditional Technique in Patients With Rectal Cancer

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ABSTRACT

Background: This was a retrospective study that evaluated the surgical outcomes of laparoscopic surgery (LS) for rectal cancer, in comparison with a case control series of open surgery (OS), during an 8-year period.

Methodology: Between October 1998 and December 2006, 203 patients with rectal malignancies underwent colectomy; 146 of them had colectomy with the traditional technique (OS), while 57 underwent resection of rectal cancer laparoscopically (LS). The LS group was compared with 60 patients from the OS group (selected from the 146 OS group patients), matched by size, sex, age, anatomical location of the tumor, type, extent of resection, and pathological stage. Data were obtained from patients' medical records. Statistical analysis was performed with the *t* test and chi-square test. All data are expressed as mean ± standard error of the mean (SEM).

Results: Mean age of the LS group was 63.7±12 years versus 69±12 years in the OS group. There were more men than women in both the laparoscopic (33 males, 24 females) and OS groups (35 men, 25 women). The mean follow-up period was 38 months and 78 months for LS and OS groups, respectively. The procedure included low anterior resection (43 in LS and 45 in OS), and 13 patients in both groups underwent abdominoperineal resection and 3 transanal resections (2 in OS and 1 in LS). Mean tumor size was 4.2±2.12cm in the LS versus 5.2±2.02cm in the OS group. Conversion to an open procedure occurred in 4 patients (6.7%), all in the first 20 cases. Postoperative complications developed in 28 patients (11.7%), 13 in the LS group and 15 in the OS group. Median operative time was longer, but median blood loss was significantly lower in the LS group. The length of hospital stay was significantly shorter for the LS group.

Conclusion: Laparoscopic surgery is feasible and safe for patients with rectal cancer and provides benefits during the postoperative period without increased morbidity or mortality.

Key Words: Laparoscopic surgery, Rectal carcinoma, Laparoscopic anterior resection, Leakage, Ileostomy, Surgical outcome.

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INTRODUCTION

Laparoscopic resection for rectal cancer has been reported to achieve acceptable short- and mid-term outcomes and long-term safety when performed by skilled laparoscopic surgeons.[1–3] Recently, some retrospective comparative studies have demonstrated several advantages in patients with rectal malignancies who underwent laparoscopic surgery compared with patients who underwent surgery with the traditional technique, including intraoperative blood loss, decreased postoperative pain, shorter hospital stay, and favorable effects on immunological status.[2–5] In addition, 2 multicenter trials, the CLASSIC[6] and the COLOR,[7] demonstrated longer operative time for patients who underwent laparoscopic surgery, a shorter hospital stay, a shorter postoperative ileus, less use of postoperative analgesics, lower postoperative pain scores, and faster return to normal activities.[8–10] However, several studies have reported the theoretical advantages of LS, such as magnification and superior exposure allowing better identification of very critical structures.[11,12]

Some other reports published recently have examined the feasibility of laparoscopy for rectal cancer.[12,13] In the context of a minimally invasive technique, the omission of a protective ileostomy has definitive advantages regarding the overall cosmetic result[11]

Low recurrence and improvement of postoperative results after total mesorectal excision (TME) support the value of removing the fat tissue around the anterolateral rectal border, known as the mesorectum.[14]

Symptomatic anastomotic leakage is the most important complication after surgical operations for rectal carcinomas. Leakage after low anterior resection can result in significant morbidity and mortality and may be associated with a higher local recurrence rate.[15,16]

The increase in sphincter-saving procedures may contribute to an increased incidence of anastomotic failure. In addition, TME potentially compromises the blood supply to the remaining rectum and thus may compromise anastomotic healing.[17–19] Removal of the mesorectum leaves a large space in the pelvis area in which a hematoma may accumulate, leading to pelvic sepsis. To avoid all these difficult situations, it is crucial to take all necessary measures.[18,19]

The goal of this study was to compare operative safety, complications, and oncological outcomes after laparoscopic resection in patients with rectal cancer in comparison with a case control series of open surgery.

MATERIALS AND METHODS

Between October 1998 and December 2006, 203 patients with rectal malignancies underwent colectomy; 146 had colectomy with the traditional technique (OS), while 57 underwent resection of rectal cancer laparoscopically (LS). The LS group was compared with 60 patients in the OS group (selected from the 146 OS patients). Laparoscopic surgery was performed by a single surgeon, while open resection was performed by 3 surgeons, all with experience in colonic malignancy operations.

All patients, before surgery, were evaluated by clinical examinations, including colonoscopy, chest radiograph, barium enema, and CT-abdominal scan.

Excluded from this study were patients with ASA IV, with T4 tumors, and severe obesity (BMI$>$30 kg/m^2), with synchronous metastasis, metachronous cancer, familiar adenomatous polyposis (FAP), histology other than adenocarcinoma, and those who did not consent to laparoscopic surgery. Finally, patients with preexisting median laparotomies were also excluded, because these patients would not even have had the minimal advantage of a better cosmetic situation.

The LS group was compared with the OS group of patients matched for sex, age, location of tumor, surgical procedure, extent of resection, and pathologic stage. The location of the tumors was defined according to the distance from the anal verge, as determined by colonoscopy: lower rectum (0 cm to 7 cm), middle (7 cm, range, 1 cm to 11 cm), and upper rectum (11 cm, range, 1 cm to 17 cm). Bowel preparation was performed the day before surgery by intestinal washout with an iso-osmotic solution (4 liters). The evening before and the morning of the operation, patients were given an enema. As antibiotic prophylaxis, all patients received a single dose of third-generation cephalosporin (2 g iv) and 500 mg of metronidazole during induction in anesthesia. A second dose of metronidazole was given intraoperatively if the surgical procedure lasted more than 4 hours. All patients underwent general anesthesia plus epidural anesthesia for the laparoscopic group patients. All patients received low molecular-weight heparin plus Daflon 500 mg as a standard prophylaxis for deep venous thrombosis. Nasogastric tube was placed intraoperatively and withdrawn immediately after the end of the surgical procedure.

Neoadjuvant chemoradiotherapy has been standardized at our institution since 2000 for T3 and T4 lesions. However, neoadjuvant therapy was used for T2N lesions located at the lower rectum to achieve a sphincter-saving procedure. Indeed, 5 patients (1 with B1 and 4 with B2 lesions in proximity to the dentate line) underwent neoadjuvant therapy. Adjuvant chemoradiotherapy was routinely performed for stages B2, C1, C2, and D (Duke's Classification), and for patients ≤75 years of age.

The dose of radiotherapy given pre- or postoperatively was 50 Gy divided into 20 fractions to 25 fractions for 4 weeks to 5 weeks. For adjuvant chemotherapy, tegafur-levamisole or 5-fluorouracil – levamisole or <Xeloda> was administered to patients with stage B2, C, and D.

We analyzed the oncological results of patients who underwent surgical rectal resection between October 1998 and December 2006. Criteria for determining recurrence include increase in carcinoembryonic antigen (CEA) level, histological confirmation, palpable disease, or clear evidence after radiological studies. Peritoneal seeding, local or regional recurrence, distal lymph node metastasis, and blood bone metastasis were considered as sites of recurrence. Local recurrence was defined as recurrence in areas continuous to the primary resection or at the site of anastomoses.

Laparoscopic Surgical Technique

All laparoscopic operations were performed by a single surgeon (ECT) with experience and skill in open and laparoscopic colorectal surgery. Pneumoperitoneum was induced by insufflations of CO_2 and was maintained between 9 mm Hg and 12 mm Hg during the entire surgical procedure. Laparoscopic operations were performed according to the technique described by Milsom and Bohm.[9] Briefly, a 4-port technique was used in most cases for both low anterior resection and abdominoperineal resection. The lymph node resection was started around the origin of the inferior mesenteric artery, which was divided by clips at the level of 1cm from its origin in all cases. The splenic flexure was fully mobilized. The rectum was then mobilized with an attempt to keep the mesorectal fascia intact. Before the division of the rectum, rectal washout was conducted using 120 mL of 5% povidone-iodine solution. The rectum then was divided (for low anterior resection procedures) by using laparoscopic linear staplers introduced from the left iliac fossa trocar, and the proximal end of the bowel was delivered through a small incision of the suprapubic trocar extended to approximately 4 cm to 6 cm, protected by a plastic cover bag. The bowel was resected extracorporeally, after an anvil was placed into the proximal colon, and an anastomosis was performed intracorporeally by means of the double-stapling technique. All patients underwent total mesorectal excision (TME). In patients with cancer at the lower rectum, TME was performed, and transverse coloplasty was fashioned extracorporeally, before the anastomosis was done, for a neorectal creation. In our department during the last 7 years, we have preferred the transverse coloplasty pouch to the J-pouch.

A diverting (protective) ileostomy was fashioned selectively according to intraoperative events, such as anastomoses close to the anal verge, positive air leak test, incomplete doughnuts, or extreme difficulty with pelvic dissection. For the abdominoperineal resection, the sigmoid colon was divided, and the total mesorectal excision was completed intracorporeally. The perineal dissection and the end colostomy were constructed in the usual manner.

Statistical Analysis

Continuous and categorical variables were analyzed using the Student *t* test and Fischer's exact test, respectively.

A *P* value <0.05 was considered to indicate a statistically significant difference. Overall and disease-free survival rates were calculated by the Kaplan-Meier method, Log Rank test, and Cox Regression proportional hazards.

RESULTS

Laparoscopic mobilization of the colon and rectum was performed in all patients. In 4 patients, 3 with considerable obesity and 1 with severe inflammation of the colon, the set time limit of 60 minutes was exceeded, and the patients were primarily converted to a midline laparotomy. All 4 patients in which the laparoscopic technique was not successful had BMI$>$28 kg/m^2. Demographic characteristics of the patients are summarized in **Table 1**. There is a significant difference between the 2 groups regarding age and sex.

Surgical data are summarized in **Table 2**. In both groups, 2 patients underwent anterior resection of the rectum with end-to-end anastomosis of the colon, 1cm to 2cm from the anal verge. In these patients, a protective ileostomy was fashioned.

Three patients, one in the LS group and 2 in the OS group, underwent intersphincteric resection and coloanal anastomoses (ISR-CAA), and a J-pouch was fashioned **(Table 2)**.

Seven patients in the LS group, and 10 patients in the OS group underwent a covering ileostomy. Symptomatic

Table 1.
Demographic Characteristics

	Open	Laparoscopic	*P* Value
Number of Patients*	60	57	NS
Age (Year range)†	68.91 ± 12.555	63.77 ± 12.714	0.032
Sex (Male/Female)*	35/25	33/24	0.022
BMI (kg/m^2 range)†	25 (21–30.3)	23 (20–27.7)	NS
Follow-up (months)	78	83	NS

*Fisher exact test.
†Data expressed as Mean ± SD; Student's t-test.
‡NS=not significant.

Table 2. Surgical Data			
	Open	Laparoscopic	*P* Value*
Year of Surgery			
1998–2000	21	19	NS
2001–2003	22	21	NS
2004–2006	17	20	NS
Rectal Tumor Location			
Upper	32	35	NS
Middle	18	18	NS
Lower	10	7	NS
Surgical Procedure			
Anterior Res	45	43	NS
Abdominoperineal Res	13	13	NS
ISR-CAA	2	1	NS
Protected Ileostomy	10	7	NS

*Fisher exact test; NS = not significant.

anastomotic dehiscence was detected in 5 patients, 3 in the OS group and 2 in the LS group, which is comparable to other reports.[13,18] All those patients subsequently underwent closure of the ileostomy **(Table 2)**.

The following details of the surgical procedure were recorded for all patients: duration of operation, operative blood loss, amount of homologous blood transfused, and number of lymph nodes collected in cancer patients. Transfusion of blood products in the perioperative period was based on hemoglobin level (<8 g/L), or on an individual basis according to the clinical condition.

Intraoperative results and postoperative complications are shown in **Tables 3** and **4**. Operative time was longer, and blood loss was significantly lower in the LS group. Postoperative recovery of bowel function was evaluated in terms of first flatus and bowel movement **(Table 3)**.

No patients were allowed an oral feeding before the first flatus occurred. Any anastomotic dehiscence with either clinical or radiologic evidence was accepted. Follow-up for infectious and noninfectious complications was performed for at least 30 days after hospital discharge with weekly office visits **(Table 4)**.

The first flatus occurred after 1.8 days in the LS group compared with 3.0 days in the OS group ($P<0.0001$). The first bowel movement occurred after 2.9 days in the LS group and 3.8 days in the OS group ($P<0.0001$). Liquid and solid intakes were started on the first and third postoperative days in the LS group **(Table 3)**, which was

Table 3. Operative Data and Recovery		
	Open Median (Range)	Laparoscopic Median (Range)
Length of Incision (mm)	190 (170–230)	75 (70–110)
Total Anesthetic Time (min)	135 (90–165)	170 (115–205)
Time to First Bowel Movement (days)	3.8 (3–7)	2.9 (2.0–5.5)
Time to Intake Liquids (days)	4.0 (3.9–7)	2.8 (2.5–5.5)
Time to Intake Solids (days)	4.8 (4.0–8)	3.7 (3.3–6.2)
Time to Discharge (days)	11 (9–17)	8 (7–13)

Table 4.
Intraoperative and Thirty Days Postoperative Complications

	Open (15 Total)	Laparoscopic (13 Total)
Insignificant Clinical Hemorrhage	1	1
Significant Clinical Hemorrhage	1	1
Bowel Injury	0	1
Bladder Disfunction-Incontinence	1	3
Bladder Injury	0	1
Post-Operative Ileus	2	1
Wound Infection	3	0
Anastomotic Rupture	1	1
Deep Vein Thrombosis	0	0
Pulmonary infection	2	1
Cardiac Insufficiency-Angina Pectoris	1	1
Anastomotic Leak	3	2

shorter than in the OS group, third and fourth day, respectively ($P<0.0001$).

Oncological data and histopathological stage are summarized in **Tables 5** and **6**. Statistically significant differences were observed between the groups regarding tumor size and pathological stage (Stages C1-C2, D).

A statistically significant correlation was found between tumor stage, number of lymph nodes infiltrated, and adjuvant therapy **(Table 7)**.

Overall survival data are indicated in **Table 8**. No statistically significant difference was observed between groups regarding overall survival; although a statistically significant correlation was found between the 2 groups regarding survival time **(Figure 1)**, tumor size **(Figure 2)**, number of lymph nodes infiltrated **(Figure 3)**, preoperative chemo-radiotherapy **(Figure 4)**, and adjuvant therapy **(Figure 5) (Table 8)**.

Hospital stay was approximately 1 week for the LS group, which was shorter compared with 10 days in the OS group. No perioperative mortalities occurred in either group (mean 30 days after surgical procedure). The rate of bowel obstruction was 3.7% (2/60) in the LS group and 7.3% (5/57) in the OS group, which is significantly increased with respect to the LS group.

Fifteen months after the end of the study, 3 patients (2 in OS and 1 in LS) developed recurrence. Two patients from every group died from causes not related to the surgical procedure.

DISCUSSION

Although laparoscopic-assisted colorectal surgery is well established for colon and upper rectal resection, there are some technical limitations involving resection of mid- and

Table 5.
Oncological Data*

	Open	Laparoscopic	95% CI	*P* Value
Tumour Size	5.29 ±2.02	4.22 ±2.12	0.27–1.85	0.009
Number of Lymph Nodes Harvested	15.55 ±5.48	14.00 ±7.16	0.8–3.95	NS
Number of Lymph Nodes Infiltrated	1.72 ±3.01	1.67 ±3.27	1.14–1.24	NS
Liver Metastases	0.12 ±0.32	0.02 ±0.13	0.008–0.19	NS

*Data expressed as mean ± SD; Student's t-test; NS = not significant.

Table 6. Pathological Stages (Dukes)		
Open	Laparoscopic	*P* Value*
A=1	A=9	NS
B1=7	B1=10	NS
B2=18	B2=21	NS
C1=11	C1=4	0.029
C2=20	C2=13	0.008
D=3	D=0	0.002

*Fisher exact test; NS = not significant.

mainly low-rectal lesions. A few studies compare short- and mid-term outcomes and quality of life in patients who underwent laparoscopic or open proctocolectomy for rectal cancer.[13,14]

Conversion of a laparoscopic procedure to open laparotomy was performed in 4 patients, all of them during the first 20 cases. This small percentage of conversions was achieved because all operations were performed by one well-trained surgical team.[20–21] The importance of one surgical team was stressed by See et al,[21] who reported a complication rate of approximately 8% when surgeons performed laparoscopic surgery with a different assistant, compared with 3% when the surgical procedure was performed by the same assistant.

Conversion itself is not necessarily a negative event, but the authors think that good selection of patients is reasonable and justified. We noted serious complications, in both groups, that required surgical intervention.

Diverting ileostomy is up to the surgeon's decision at the moment of surgery. Some surgeons routinely affect a diverting ileostomy for laparoscopy low-anterior resection, in the management of malignancies very close to the dentate line.[15,17–19] In our department, a protective ileostomy was performed in cases with anastomoses lower than 4cm to 5cm from the anal verge.

Since the introduction of total mesorectal excision (TME) by Heald,[14] TME has become the accepted standard for rectal cancer surgery. The low recurrence and improved survival rates in TME series support the crucial value of removing the fatty tissue around the rectum, known as mesorectum.[14,16] In the multiple regression analysis, the absence of pelvic drainage after TME and the absence of a stoma were the 2 factors significantly associated with high anastomotic dehiscence and an increase in local recurrence.[16–18]

After TME surgery, a large presacral space remains in which a seroma or hematoma may develop, and this constitutes excellent material for bacteria. Pelvic drainage may prevent this process. Several trials, neverthe-

Table 7.
Correlation Between Survival and Oncological Data*

	Mean	HR	95% CI	*P* Value
Stage (Dukes)	117	1.21	0.71–2.07	0.47
Stage A	10	0.27	0.03–0.03	0.26
Stage B1	17	0.07	0.06–0.85	0.19
Stage B2	40	0.24	0.49–1.21	0.03
Stage C1	15	0.16	0.22–1.21	0.08
Stage C2	32	0.39	0.84–1.83	0.07
Stage D	3	-	-	-
Tumor Size	4.74	1.00	0.74–1.35	0.98
Number of Lymph Nodes Harvested	14.78	0.99	0.90–0.71	0.83
Number of Lymph Nodes Infiltrated	1.62	1.25	1.06–0.74	0.007
Neoadjuvant Therapy	112	1.33	0.11–0.95	0.72
Adjuvant Therapy	115	0.32	0.09–1.12	0.04

*Cox regression.

Table 8.
Survival Data

	Mean Open/Laparoscopic	HR	95% CI	*P* Value
Open vs. Laparoscopic	71.49/82.50		62.87–80.11/75.54–89.45	0.11*
Tumor Size	5.29/4.22	1.49	1.03–2.15	0.031†
Tumor Stage (Dukes)	60/57	1.15	0.95–1.39	0.34†
Stage A	1/9	7.14	0.89–57.18	0.06†
Stage B1	7/10	2.09	0.26–16.81	0.48†
Stage B2	18/22	1.55	0.47–5.04	0.46†
Stage C1	11/4	0.41	0.05–3.39	0.41†
Stage C2	20/12	1.89	0.68–5.29	0.22†
Stage D	3/0	-	-	-
No of lymph nodes harvested	15.43/14.13	0.99	0.9–1.10	0.93†
No of lymph odes infiltrated	1.69/1.55	1.67	1.29–2.16	<0.0001†
Neoadjuvant Therapy	4/7	15.83	1.04–249.46	0.047†
Adjuvant Therapy	48/29	0.008	0.001–0.78	<0.0001†

*Log rank.
†Cox regression.

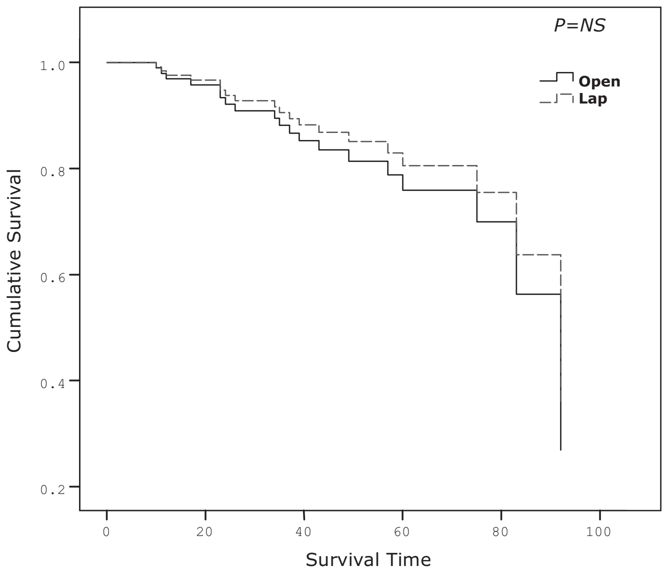

Figure 1. Overall survival between the groups.

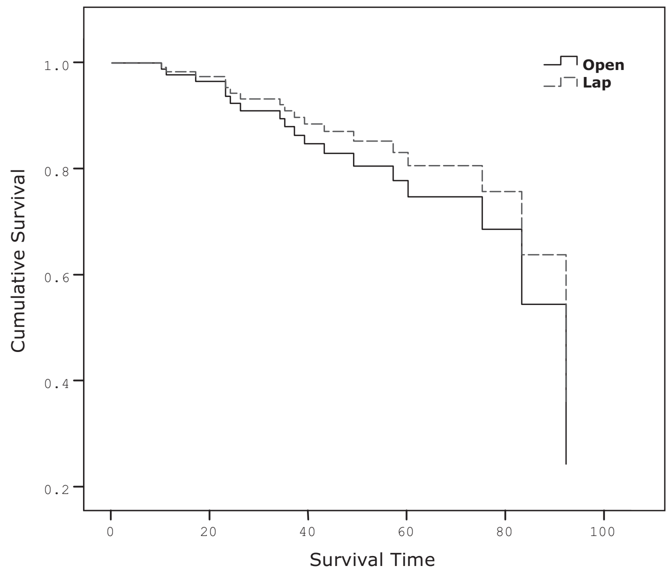

Figure 2. Survival function for tumor size.

less, have failed to show a benefit of pelvic drainage in all cases.[16–18]

In our study, patients with very low rectal tumors were found to be at risk of anastomotic leak, and so, both groups may benefit from fecal diversion. In many studies, as in the present one, the decision to construct a stoma was left to the discretion of the surgeon.[18]

Previous studies have reported an anastomotic leak rate from 7.2% to 20% in patients who underwent laparoscopic low anterior resection.[13,18,19] Therefore, some authors rec-

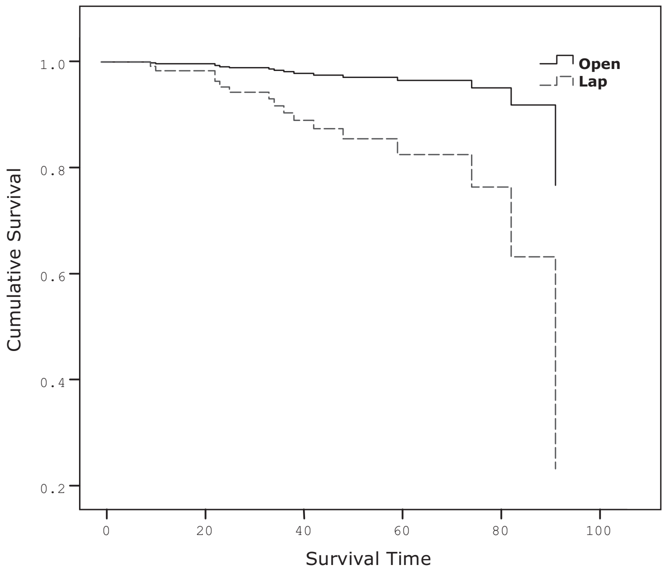

Figure 3. Survival function for number of infiltrated lymph node.

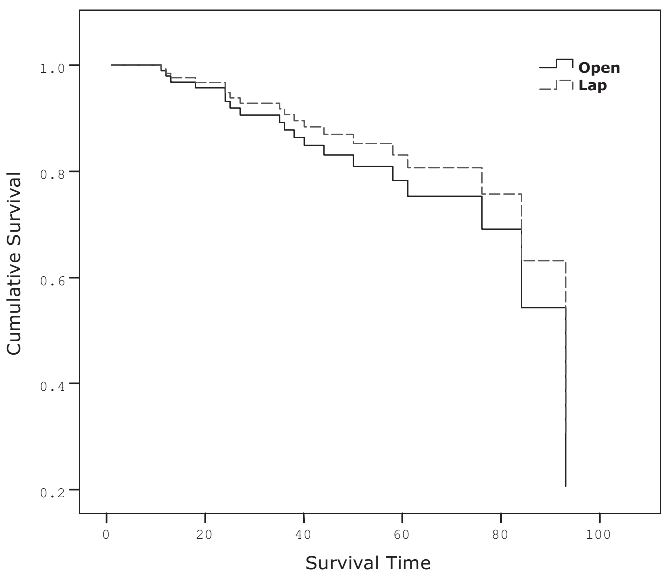

Figure 4. Survival function for neoadjuvant chemotherapy.

ommend a covering ileostomy as a routine part of this procedure.[13]

In our study, anastomotic leakage occurred in 5 patients (4.3%), 3 of them in the OS group and 2 in the LS group. The anastomotic leak rate in our study was similar to that in other studies between OS and LS groups. A protective stoma was constructed in 17 patients (13%), 10 in the group operated on with the traditional technique and 7 in

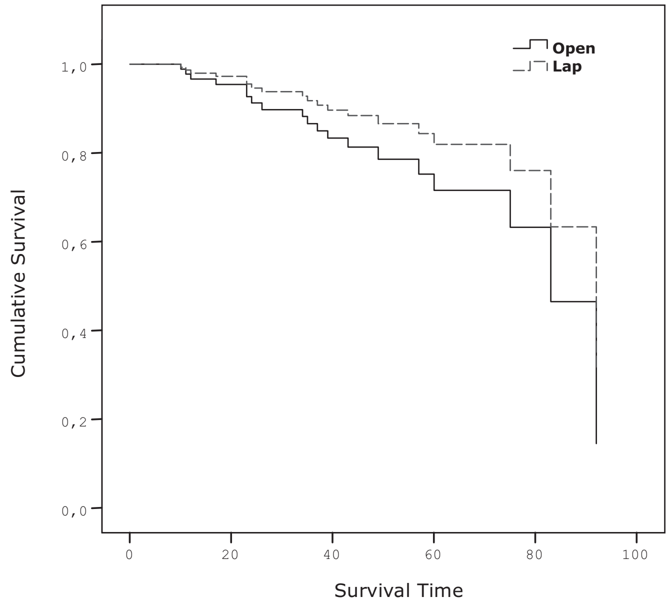

Figure 5. Survival function for adjuvant chemotherapy.

those patients who underwent laparoscopic resection. Increased risk of leak in very low anastomoses is a well-known concern after open rectal surgery.[19–21] During laparoscopic rectal resection, multiple cartridges (2 or 3 usually) for the linear stapling device are used.[22–25] Staplers used multiple times may lead to small defects between the stapler lines, thus causing anastomotic dehiscence. During open surgery, on the other hand, usually only one cartridge is applied even for the division of a large volume of rectum.

In 3 patients with tumor 1cm from the dentate line, laparoscopic intersphincteric rectal resection and hand-sewn colon-anal anastomosis (ISR-CAA) was performed. For these patients, a J-pouch with covering ileostomy was fashioned. Having seen the good results achieved with the transverse coloplasty, we prefer to perform this technique instead of the J pouch.[26–28] However in 3 such patients, the tumor location was very low, and it was easier to create a J-pouch.

In a few series, some surgeons expected increased surgical morbidity as a result of irradiation.[29–30] In some reports, it has been shown that preoperative radiotherapy is a safe treatment with no increase in the surgical complication rate.[29] There was no significant association between leakage and short-term neoadjuvant radiotherapy, which has become part of the standard regimen for rectal cancer treatment in many European countries and Japan.[29–30]

Regarding oncological results, which are very important in terms of cancer surgery, 3 RCT occurred in patients with colon and upper rectal cancer, indicating that the outcome of LS is equal to or better than that of OS.[20,21]

Analysis of operative variables confirmed that laparoscopic surgery (in the treatment of rectal cancer) took longer, caused less bleeding, and the need for homologous blood transfusion was reduced, compared with the these things in the OS group.[22,27,28]

Only the duration of surgery was longer in the LS group, and this is related to the increase in postoperative complications.[27,28,31]

Blood transfusion has been previously identified as the most important factor in postoperative complications.[22] It is very important to avoid administering homologous blood to the patient with rectal cancer who underwent curative surgery, because of the increased risk of postoperative complications.[23–25] At our institution, blood transfusion was administrated to 7 patients, 5 in the OS and 2 in the LS group ($P<0.0001$).

The LS group had a significantly lower postoperative infection rate than the OS group had. The most relevant effect in the LS group was the reduction in wound infections, which is in accordance with that in previous studies. Minimal wound trauma, shorter incision, and less manipulation in the intestine were factors involved in decreasing wound infection and postoperative ileus in the LS group.[20,21]

One of the advantages of LS for rectal cancer is the magnification of the operative field; thus, the surgeon can safely mobilize the rectum because of the easy identification of the loose connective tissue between the mesorectum and the surrounding tissues, such as the hypogastric nerve and the pelvic nerve, which is not always easy to recognize under direct vision during OS. Another advantage of LS is that everyone participating in the surgical procedure can have the same field of view.

Patients who underwent LS had a faster recovery of bowel function than patients did who had open surgery.

CONCLUSION

The findings of this study demonstrate that LS for rectal cancer can be performed safely by an experienced team; it reduces the rate of postoperative complications, the need for blood transfusions, infections, and the length of hospital stay. In an attempt to minimize the risk of clinical leakage, we recommend construction of a protective ileostomy, which seems advisable for patients with a 4-cm to 5-cm anastomosis from the anal verge. Placement of at least one drain after TME for rectal cancer is also recommended.

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