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Comparison of hand-assisted laparoscopic surgery and conventional laparotomy for rectal cancer: Interim results from a single center

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Abstract. Minimally invasive laparoscopic surgery has become widespread and the indications for such surgery have recently been extended to various conditions, including rectal cancer. The objective of this study was to compare the clinical outcome of hand-assisted laparoscopic surgery (HALS) and conventional laparotomy (CL) in patients with rectal cancer. Patients who underwent radical resection of stage I-III primary rectal cancer (n=111) were classified into those receiving HALS (n=57) and those receiving CL (n=54); the two groups were matched for stage and postoperative treatment. The 3-year relapse-free survival (3Y-RFS) and 3-year overall survival (3Y-OS) were calculated and compared between the two groups. Intraoperative blood loss, operating time, postoperative hospital stay and complications were also compared between the two groups. There were no significant differences in 3Y-RFS or 3Y-OS between the HALS and CL groups for patients with all-stage (I, II and III) rectal cancer. The mean (median) intraoperative blood loss was 344.0 (247.0) ml in the HALS group vs. 807.5 (555.5) ml in the CL group (P<0.001). The mean (median) postoperative hospital stay was 19.8 (17) and 25.5 (18.3) days, respectively (P=0.039). There were no significant differences in the operating time or the incidence of complications between the two groups. Based on these results, HALS was found to be comparable to CL regarding survival, while achieving less blood loss and a superior cosmetic outcome. However, longer follow-up is required to confirm these findings.

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Abbreviations: HALS, hand-assisted laparoscopic surgery; CL, conventional laparotomy; LACS, laparoscopy-assisted colorectal surgery

Key words: rectal cancer, hand-assisted laparoscopic surgery, conventional laparotomy, laparoscopy-assisted colorectal surgery, laparoscopic surgery

Introduction

Over the last few years, minimally invasive laparoscopic surgery has become widespread. The indications for such surgery have been extended to various conditions, including additional bowel resection for stage I rectal cancer, radical resection of stage II or III rectal cancer and palliative surgery in patients with stage IV rectal cancer (1-6). With conventional laparotomy (CL) for rectal cancer, it is difficult to visualize areas such as the pelvic floor, the ventral part of the bladder and the posterior to apical regions of the prostate and almost blind manipulation is required. By contrast, endoscopic magnification and viewing a monitor allows procedures to be performed more safely, although the difficulty of rectal cancer surgery increases with the depth of the lesion in the pelvis, particularly lower rectal cancer located at the pelvic floor (4). In Japan, pure laparoscopy-assisted colorectal surgery (LACS) is frequently performed using 5-6 ports, including a camera port and a small incision of 35-45 mm for anastomosis. However, 4 forceps are required for several procedures in pure LACS; therefore, at least 2 surgeons skilled in LACS must participate in the operation, while the long operating time puts significant pressure on the anesthesiologists and the availability of operating theaters. In addition, LACS requires additional education and technical guidance, as well as costly equipment and surgical materials; thus, performing pure LACS at medium-sized hospitals with 400-500 beds is associated with various problems (4-8). The majority of the studies comparing pure LACS with CL demonstrated that the former method is associated with a lower incidence of wound infections and a shorter hospital stay, while achieving a comparable or superior survival, with a more acceptable cosmetic outcome (7-10). However, hand-assisted laparoscopic surgery (HALS) and hybrid HALS (HH), which are based on manipulation under direct vision, are more popular compared to pure LACS in Europe and the United States. HH has the following advantages: i) It allows safe palpation and grasping with the left

hand according to the techniques learned for laparotomy, which allows smooth handling of large, heavy tumors and also allows the surgeon to rapidly and easily pull the resected intestines away from the pelvic floor under direct vision, as in laparotomy; ii) since HH is based on laparotomy, the operating time is relatively short; and iii) it does not require a long time to learn the skills necessary to perform HH (8,9,11-17). In Japan, CL accounts for ~50% of rectal cancer surgery and pure LACS accounts for ~30-40%, with HALS and small incision surgery constituting the remaining 10-20% (18). The majority of the studies comparing HALS and pure LACS have demonstrated that the operating time is shorter with HALS and the rate of conversion to open laparotomy is low; HALS may thus be considered as a surgical technique between CL and pure LACS (8,9,19-23). In Japan, HALS was widely used as an adjunctive method for a brief period until pure LACS was introduced in 2000; however, the use of HALS has noticeably decreased since the standardization of pure LACS. Therefore, although certain single-center studies on HALS have been performed overseas, no such report has been published in Japan (9,24,25). Accordingly, the objective of this study was to compare the clinical outcome of HALS and CL in patients with rectal cancer treated at a single center in Japan.

Patients and methods

Patients. A total of 850 patients underwent curative resection of primary colorectal cancer at Tokai University Hachioji Hospital (Tokyo, Japan) between April, 2002 and December, 2012. HALS was employed to treat colorectal cancer from July, 2007 onwards and was used in at least 350 patients. A total of 54 patients who underwent conventional CL prior to the introduction of HALS were selected from the 850 patients as stage-matched historical controls, whereas the HALS group comprised 57 patients. The mean/median age was 65.4/65.0 years (range, 55-81 years) in the HALS group and 67.0/68.5 years (range, 35-92 years) in the CL group (P=0.095) (Table IA). Of the 57 patients in the HALS group, 43 (75.4%) were male and 14 (24.6%) were female; of the 54 CL patients, 35 (64.8%) were male and 19 (35.2%) were female, with no significant differences between the two groups (P=0.221) (Table IB). As regards tumor location, the tumor was located at the rectosigmoid region in 20 patients (35.1%) from the HALS group and 20 (37.0%) from the CL group (P=0.831); in the upper rectum in 21 patients (36.8%) from the HALS group and 14 (25.9%) from the CL group (P=0.216); and in the lower rectum in 16 patients (28.1%) from the HALS group and 20 (37.0%) from the CL group (P=0.313). There were no significant differences between the two groups (Table IC). A total of 11 patients (19.3%) in the HALS group and 12 (22.2%) in the CL group underwent anterior resection (P=0.704); 39 patients (68.4%) in the HALS group and 33 (61.1%) in the CL group underwent low anterior resection (P=0.420); and 7 patients (12.3%) in the HALS group and 9 (16.7%) in the CL group underwent Miles' operation (P=0.511). There were no significant differences between the two groups (Table. IIA).

The CL group included 54 patients who underwent radical resection (stage I, 10 patients; stage II, 20 patients; and stage III, 24 patients) prior to August, 2007 and received the same postoperative adjuvant chemotherapy and follow-up as the those in the HALS group (Table IIB). These historical controls were matched for stage with the 57 patients who underwent HALS (stage I, 17 patients; stage II, 14 patients; and stage III, 26 patients) from 2007 onwards. For all patients in both groups, the operative indications were as follows: A performance status of 0-2, no severe cardiopulmonary complications, no lateral lymph node metastasis or invasion of multiple organs and tumor not filling the pelvic cavity prior to surgery (4,26,27).

Table I. Comparison of patient age, gender and tumor location between the HALS (n=57) and CL (n=54) groups.

A, Comparison of patient age

Age (years)	HALS	CL	P-value[a]
Average	65.4	67.0	0.095
Median (range)	65.0 (55-81)	68.5 (35-92)	

B, Comparison of patient gender

Gender	HALS, no. (%)	CL, no. (%)	P-value[b]
Male	43 (75.4)	35 (64.8)	0.221
Female	14 (24.6)	19 (35.2)	

C, Comparison of tumor location

Location	HALS, no. (%)	CL, no. (%)	P-value[b]
RS	20 (35.1)	20 (37.0)	0.831
Ra	21 (36.8)	14 (25.9)	0.216
Rb	16 (28.1)	20 (37.0)	0.313

[a]Mann-Whitney U test. [b]Chi-square test. There were no significant differences in patient age, gender and tumor location between the two groups. HALS, hand-assisted laparoscopic surgery; CL, conventional laparotomy; RS, rectosigmoid; Ra, rectum above peritoneal reflection; Rb, rectum below peritoneal reflection.

The present study was approved by the Institutional Review Board of Tokai University Hachioji Hospital and all the patients provided written informed consent.

Treatment. CL involved a midline laparotomy with an incision of 30 cm or longer, whereas HALS was performed with 3 ports (rectum, 5/12/5 mm) and a vertical incision of ~45-55 mm in the umbilical region (4,26,27). In accordance with the Japanese General Rules for Classification of Colorectal Carcinoma, a D2,3 resection was performed and at least 12 lymph nodes were harvested in all the patients from both groups (28-30). No postoperative adjuvant chemotherapy was administered to stage I patients; oral anticancer agents were administered to stage II patients (400 mg/m^2 tegafur/uracil and 3 g of polysaccharide K 5 days/week for at least 6 months); and modified 5-fluorouracil/leucovorin (5-FU/LV) or modified FOLFIRI (5-FU/LV + irinotecan: 85 mg/m^2 of irinotecan twice a month and 350 mg/m^2 of 5-FU plus 150 mg/m^2 LV on 5 consecutive

Table II. Comparison of operative method and tumor stage between the HALS (n=57) and CL (n=54) groups.

A, Comparison of operative method

Operative method	HALS, no. (%)	CL, no. (%)	P-value[a]
Anterior resection	11 (19.3)	12 (22.2)	0.704
Low anterior resection	39 (68.4)	33 (61.1)	0.420
Miles' operation	7 (12.3)	9 (16.7)	0.511

B, Comparison of tumor stage

Tumor stage	HALS, no. (%)	CL, no. (%)	P-value[a]
I	17 (29.8)	10 (18.5)	0.165
II	14 (24.6)	20 (37.0)	0.154
III	26 (45.6)	24 (44.4)	0.901

[a]Chi-square test. There were no significant differences in operative method and tumor stage between the two groups. HALS, hand-assisted laparoscopic surgery; CL, conventional laparotomy.

days/month) was administered to stage III patients for at least 6 months (31-36).

Survival. To identify metastasis/recurrence, we performed ultrasound scan/computerized tomography (US/CT) and measured tumor markers 3-4 times/year. If metastasis/recurrence was identified by both US and CT, this was defined as metastasis/recurrence in the present study (31-36). For patients at each stage (I, II and III) from the two groups, the 3-year relapse-free survival (3Y-RFS) and 3-year overall survival (3Y-OS) were calculated. The mean and median values of blood loss, operating time and postoperative hospital stay, as well as the rate of conversion to open laparotomy (only in the HALS group) were also calculated. Furthermore, we compared postoperative complications, such as wound infection, ileus, anastomotic leakage and re-operation, between the two groups.

Statistical analysis. The Kaplan-Meier method was employed to estimate 3Y-RFS and 3Y-OS, while the log-rank test and hazard ratio (HR) [(95% confidence interval (CI)] were used for comparisons between the two groups. For other analyses, the χ^2 test and Mann-Whitney U test were used. P<0.05 was considered to indicate a statistically significant difference. Analyses were performed with SPSS 21.0 statistical software (IBM Corporation, Armonk, NY, USA).

Results

Comparison of survival between the two groups. The 3Y-RFS of patients with stage I, II and III disease (n=111) was 80.7% in the HALS group (n=57) and 77.4% in the CL group (n=54) [P=0.628; HR=0.87 (95% CI: 0.42-1.80)] (Fig. 1). In addition, the 3Y-OS was 96.5% in the HALS group (n=57) vs. 86.8% in the CL group (n=54) [P=0.064; HR=0.27 (95% CI: 0.06-1.25)] (Fig. 2). The 3-year follow-up rate was 98.3% in the HALS group and 96.3% in the CL group (mean, 97.3%).

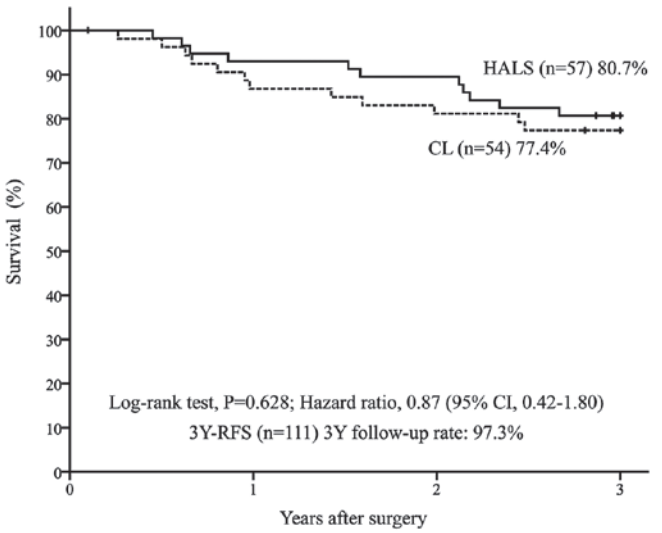

Figure 1. The 3-year relapse-free survival rate (3Y-RFS) of the HALS group and the CL group were calculated by the Kaplan-Meier method and compared with the log-rank test and hazard ratio with 95% confidence interval (CI). The 3-year mean follow-up rate was 97.3%. HALS, hand-assisted laparoscopic surgery; CL, conventional laparotomy.

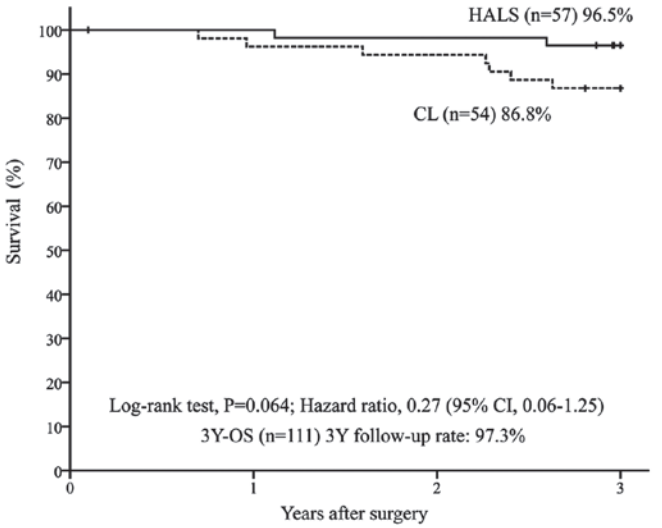

Figure 2. The 3-year overall survival rate (3Y-OS) of the HALS group and the CL group were calculated by the Kaplan-Meier method and compared with the log-rank test and hazard ratio with 95% confidence interval (CI). The 3-year mean follow-up rate was 97.3%. HALS, hand-assisted laparoscopic surgery; CL, conventional laparotomy.

Intraoperative factors and hospital stay. The mean/median intraoperative blood loss was 344.0/247.0 (range, 15-1969) ml in the HALS group (n=57) and 807.5/555.5 (121-4293) ml in the CL group (n=54) (P<0.001) (Table III). The mean/median operating time was 3 h 51 min/3 h 34 min (1 h 57 min-7 h 49 min) in the HALS group (n=57) and 3 h 52 min/3 h 38 min

Table III. Intraoperative factors and hospital stay in the HALS and CL groups.

Variables	HALS (n=57)	CL (n=54)	P-value[a]
Blood loss[b]			<0.001
Mean	344.0 ml	807.5 ml	
Median (range)	247.0 (15-1,969) ml	555.5 (121-4,293) ml	
Operating time			
Mean	3 h 51 min	3 h 52 min	0.454
Median (range)	3 h 34 min (1 h 57 min-7 h 49 min)	3 h 38 min (2 h 06 min-7 h 12 min)	
Postoperative hospital stay			
Mean	19.8 days	25.5 days	0.039
Median (range)	17.0 (8-55) days	18.5 (12-97) days	

[a]Mann-Whitney U test. [b]Data unknown for 1 patient in the HALS and 4 patients in the CL group. HALS, hand-assisted laparoscopic surgery; CL, conventional laparotomy.

(2 h 06 min-7 h 12 min) in the CL group (n=54) (P=0.454) (Table III). The mean/median postoperative hospital stay was 19.8/17.0 (8-55) days in the HALS group (n=57) and 25.5/18.5 (12-97) days in the CL group (n=54) (P=0.039) (Table III).

Postoperative complications. In the HALS group (n=57), the postoperative complications included wound infection in 4 patients (7.0%), ileus in 4 patients (7.0%), anastomotic leakage in 3 patients (5.3%), urinary tract injury in 1 patient (1.8%) and re-operation in 2 patients (3.5%). There were no cases of conversion to open laparotomy (0.0%) (Table IV). In the CL group (n=54), these complications occurred in 9 (16.7%), 2 (3.7%), 3 (5.6%), 4 (7.4%) and 3 patients (5.6%), respectively; there were no significant differences in the incidence of complications between the two groups (Table IV).

Table IV. Postoperative complications in the HALS and CL groups.

Complications	HALS, no (%) (n=57)	CL, no (%) (n=54)	P-value[a]
Wound infection	4 (7.0)	9 (16.7)	0.114
Ileus	4 (7.0)	2 (3.7)	0.440
Anastomotic leakage	3 (5.3)	3 (5.6)	0.946
Urinary tract injury	1 (1.8)	4 (7.4)	0.151
Re-operation	2 (3.5)	3 (5.6)	0.603
Others	3 (5.3)	5 (9.3)	0.416
Conversion to CL	0 (0.0)		

[a]Chi-square test. HALS, hand-assisted laparoscopic surgery; CL, conventional laparotomy.

Discussion

In Japan, ~30-40% of rectal cancer surgeries are performed by pure LACS, CL accounts for ~50%, while HALS and small incision surgery are used for the remaining 10-20% (18). Since pure LACS has rapidly been adopted over the last few years, several studies comparing pure LACS with CL or HALS have been reported (8,9,19-23). However, there is a major problem with the majority of the studies. Usually, single-center comparison of surgical procedures employs the CL group as a control; however, it is difficult to avoid bias of background factors in studies of pure LACS or HALS, as these procedures tend to be used for low-risk patients with a relatively good general condition, who are able to tolerate the oblique position with the head down, or patients with early-stage disease. In addition, it may be difficult to achieve unification of second-line treatment, including postoperative chemotherapy and radiotherapy, as well as treatment following recurrence (4-10). Moreover, if national clinical databases or guidelines are used as controls, the study becomes a stage-stratified comparison of outcomes with the national standards, which is not appropriate for comparing surgical procedures. In our study, the CL group was selected from patients who underwent surgery prior to the introduction of HALS and we ensured that they were matched for stage and received the same postoperative adjuvant chemotherapy as the HALS group. All operations in both groups were performed by Mukai *et al* (4,27), so the management of stage I, II and III rectal cancer was standardized and at least 6 months of treatment was completed by >80% of the patients in the two groups (data not shown). In addition, <20% of the patients were censored from our database, including those with unknown details/dropout, which conforms to the Japanese Society for Cancer of the Colon and Rectum Guidelines 2010 for the Treatment of Colorectal Cancer and the database used in this study had a total censored rate of 11.9% for the HALS group vs. 1.8% for the CL group (P=0.001, data not shown). Furthermore, all the patients were followed up for ≥3 years, with a 3-year follow-up rate of 98.3% for the HALS group and 96.3% for the CL group. We are planning to perform a final analysis in the next 2 years.

Studies comparing pure LACS with CL have identified problems with the former, including a longer operating time and increased cost, although the hospital stay is shorter and analgesic use is decreased (7-10). There are also other problems with performing pure LACS at medium-sized hospitals with 400-500 beds, including the need for skilled surgeons, the training requirements, the pressure on the anesthesiologists due to longer operations, longer occupation of operating theaters and greater consumption of materials. The comparison of pure LACS with HALS has also identified problems, such as the slower learning curve for pure LACS, additional time required and differences in the conversion rate to open surgery (8,9,19-23). It has been reported that HALS is associated with a markedly lower conversion rate compared to pure LACS, with the rate being 0.0% (0/57 patients) in our study. This result indicates that preoperative diagnosis and our indications for HALS were strict and appropriate (2,4,7). In addition, there was less blood loss and a shorter hospital stay with HALS compared to CL, suggesting that HALS may be performed safely based on strict indications by employing the magnified view obtained with laparoscopy.

In conclusion, HALS is a safe and reliable procedure that utilizes the same left-hand manipulation as CL and allows palpation/touch as it is positioned between pure LACS and CL. Since HALS may be performed relatively easily at a low cost, we consider it to be an excellent therapeutic option that deserves re-evaluation, particularly in Japan, due to the decreasing availability of surgeons and anesthesiologists.

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