OXFORD

BJS Open, 2021, zrab083
DOI: 10.1093/bjsopen/zrab083
Original Article

Outcomes of robot-assisted *versus* conventional laparoscopic low anterior resection in patients with rectal cancer: propensity-matched analysis of the National Clinical Database in Japan

T. Matsuyama [1], H. Endo [2], H. Yamamoto[2], I. Takemasa[3], K. Uehara [4], T. Hanai[5], H. Miyata[2], T. Kimura[6], H. Hasegawa[6], Y. Kakeji[7], M. Inomata[8], Y. Kitagawa[9] and Y. Kinugasa[1,*]

[1]Department of Gastrointestinal Surgery, Tokyo Medical and Dental University Graduate School of Medicine, Tokyo, Japan
[2]Department of Healthcare Quality Assessment, Graduate School of Medicine, University of Tokyo, Tokyo, Japan
[3]Department of Surgery, Surgical Oncology and Science, Sapporo Medical University School of Medicine, Sapporo, Japan
[4]Division of Surgical Oncology, Department of Surgery, Nagoya University Graduate School of Medicine, Aichi, Japan
[5]Department of Surgery, Fujita Health University School of Medicine, Aichi, Japan
[6]Project Management Subcommittee, Japanese Society of Gastroenterological Surgery, Tokyo, Japan
[7]Database Committee, Japanese Society of Gastroenterological Surgery, Tokyo, Japan
[8]Department of Gastroenterological and Paediatric Surgery, Oita University Faculty of Medicine, Oita, Japan
[9]Japanese Society of Gastroenterological Surgery, Tokyo, Japan

Correspondence to: Department of Gastrointestinal Surgery, Tokyo Medical and Dental University Graduate School of Medicine, 1-5-45 Yushima, Bunkyo-Ku, Tokyo 113-8510, Japan (e-mail: kinugasa.srg1@tmd.ac.jp)

Abstract

Background: Robot-assisted laparoscopic surgery has several advantages over conventional laparoscopy. However, population-based comparative studies for low anterior resection are limited. This article aimed to compare peri-operative results of robot-assisted low anterior resection (RALAR) and laparoscopy

Methods: This retrospective cohort study used data from patients treated with RALAR or conventional laparoscopic low anterior resection (CLLAR) between October 2018 and December 2019, as recorded in the Japanese National Clinical Database, a data set registering clinical information, perioperative outcomes, and mortality. Of note, the registry does not include information on the tumour location (centimetres from the anal verge) and diverting stoma creation. Perioperative outcomes, including rate of conversion to open surgery, were compared between RALAR and CLLAR groups. Confounding factors were adjusted for using propensity score matching.

Results: Of 21 415 patients treated during the study interval, 20 220 were reviewed. Two homogeneous groups of 2843 patients were created by propensity score matching. The conversion rate to open surgery was significantly lower in the RALAR group than in the CLLAR group (0.7 *versus* 2.0 per cent; $P < 0.001$). The RALAR group had a longer operating time (median: 352 *versus* 283 min; $P < 0.001$), less intraoperative blood loss (15 *versus* 20 ml; $P < 0.001$), a lower in-hospital mortality rate (0.1 *versus* 0.5 per cent; $P = 0.007$), and a shorter postoperative hospital stay (median: 13 *versus* 14 days; $P < 0.001$) compared with the CLLAR group. The CLLAR group had a lower rate of readmission within 30 days (2.4 *versus* 3.3 per cent; $P = 0.045$).

Conclusion: These data highlight the reduced conversion rate, in-hospital mortality rate, intraoperative blood loss, and length of postoperative hospital stay for rectal cancer surgery in patients treated using robot-assisted laparoscopic surgery compared with laparoscopic low anterior resection.

Introduction

Minimally invasive surgery has been used extensively in various types of surgery, including low anterior resection (LAR). Recent RCTs have shown that laparoscopic LAR is associated with less blood loss, faster bowel recovery, and a shorter postoperative hospital stay than open surgery. However, laparoscopic surgery has several drawbacks, including the requirement for straight and inflexible devices, uncomfortable ergonomic positions, and the fulcrum effect that makes hand–eye coordination difficult[1]. Two recent large, multicentre RCTs[2,3] revealed higher positive circumferential resection margin (CRM) rates in laparoscopic surgery than in open surgery for rectal cancer, which might be related to technical difficulty in the narrow pelvis during open surgery.

Robot-assisted laparoscopic surgery (RALS) is the latest advance in minimally invasive surgery. It provides several advantages over conventional laparoscopic surgery (CLS) in terms of use of advanced technologies, such as articulating instruments, immersive three-dimensional view, enhanced dexterity with

Received: April 14, 2021. **Accepted:** August 02, 2021

tremor filtration, and motion scaling. Although the initial results, including those from the Japanese high-volume centre, are promising for improving short- and long-term outcomes and urological function[4,5], there is currently no robust clinical evidence supporting the benefit of RALS for rectal cancer. Therefore, further reliable data are needed to build concrete evidence for the benefits of RALS for rectal cancer.

In 2011, the National Clinical Database (NCD) started a nationwide registry maintained by the Japan Society of Gastroenterological Surgery in Japan. This NCD system has covered more than 95 per cent of gastrointestinal operations performed in Japan[6]. In 2019, the number of procedures registered in the NCD was 1.56 million, and the cumulative total reached approximately 12 million. RALS for rectal cancer has been covered by national insurance since April 2018 and has spread rapidly nationwide. Preoperative NCD registration has been mandatory since October 2018 to evaluate the safety and benefits of RALS. Although population-based studies, such as those using the NCD registry, can address treatment outcomes worldwide and include an adequate number of patients for background adjustment, few population-based, extensive cohort studies[7] have been conducted to evaluate the safety and benefit of RALS by comparing short-term clinical outcomes of robot-assisted (RALAR) *versus* conventional (CLLAR) laparoscopic LAR for rectal cancer.

This paper aimed to compare the short-term outcomes of these two procedures using the NCD registry with propensity score matching analysis.

Methods

Patients and data source

This retrospective comparative study used the NCD, a nationwide surgical registration system in Japan. The NCD contains perioperative clinical information, including patient's co-morbidities, intraoperative outcomes, postoperative mortality, and intraoperative and postoperative morbidities. The clinical data from patients with rectal adenocarcinoma who underwent RALAR or CLLAR between October 2018 and December 2019 were reviewed. Rectal adenocarcinoma was defined as a tumour located below the promontory based on barium enema examination. Of note, LAR was defined as a standard surgical procedure, including dissection and anastomosis conducted below the peritoneal reflection, for mid to low rectal cancer. The data set did not include information on tumour location (centimetres from the anal verge) and diverting stoma creation. LAR with non-restorative procedures (Hartmann's procedure) and Miles' resections were excluded from this study . Patients whose tumours were not primary rectal adenocarcinomas and who had missing data were also excluded. The Ethics Committee of Tokyo Medical and Dental University approved this study, and waived the need to obtain informed consent because the NCD contained only deidentified data (M2020-142).

Study endpoints

Intraoperative and short-term postoperative outcomes were compared between the two groups. The primary endpoint was the rate of conversion to open surgery. Secondary endpoints were duration of operation, intraoperative blood loss, intraoperative transfusion, R0 resection rate, in-hospital mortality, postoperative mortality within 30 days, reoperation within 30 days, readmission within 30 days, postoperative overall morbidity (based on the Clavien–Dindo classification), postoperative complications, and duration of hospital stay.

Propensity score matching

Propensity score matching between patients who underwent RALAR and CLLAR was conducted to minimize selection bias arising from a retrospective study. Co-variables used for propensity score matching included those considered confounders or risk factors based on the literature and clinical practice: age, sex, BMI, activities of daily living (ADL; the need for any assistance), ASA physical status grade, smoking status (Brinkman index), habitual alcohol consumption, chronic steroid use, weight loss (at least 10 per cent within 6 months), hypertension, diabetes mellitus, chronic obstructive pulmonary disease, congestive heart failure, dialysis, ischaemic heart disease (history of myocardial infarction, percutaneous coronary intervention, angina), cerebrovascular disease, bleeding disorder, preoperative transfusion, neoadjuvant chemotherapy, neoadjuvant radiotherapy, and clinical T, N, and M categories. Propensity scores for each patient were obtained using a multivariable logistic regression model based on patient characteristics. Nearest-neighbour matching was performed using a caliper width of 0.2, standard deviations of the logit of the estimated propensity score for one-to-one pair matching without replacement. The balance of the propensity-matched groups was assessed using the standardized mean difference (SMD), with absolute values less than 0.1 considered well balanced between the two groups.

Statistical analysis

Continuous variables are shown as median (i.q.r.), and categorical variables as numbers with percentages. Outcomes in matched cohorts were compared using the McNemar test or McNemar's exact test for categorical variables and the Wilcoxon signed-rank test for continuous variables. In prematched cohorts, these outcomes were compared using Pearson's χ^2 test or Fisher's exact test for categorical variables and the Wilcoxon rank-sum test for continuous variables. All P values were two-sided, and $P < 0.050$ was considered statistically significant. Statistical analyses were performed using R version 3.6.3 (R Foundation for Statistical Computing, Vienna, Austria).

Results

Baseline characteristics

A total of 21 415 patients underwent RALAR or CLLAR during the study interval. Among these, 838 patients who did not have primary rectal adenocarcinoma and 357 with missing data were excluded. Accordingly, some 20 220 eligible patients (CLLAR: 17 377 patients, 85.9 per cent; RALAR: 2843 patients, 14.1 per cent) were identified. After propensity score matching, some 2843 matched pairs were created (*Fig. 1*).

Patient baseline characteristics before and after propensity score matching are shown in *Table 1*. Before propensity score matching, several baseline characteristics were imbalanced between the two groups (SMD 0.1 or higher), including age, ADL, ASA grade, hypertension, preoperative chemotherapy, and clinical T category. After propensity score matching, all the co-variables were well balanced, as evidenced by an SMD of less than 0.100.

Intraoperative and postoperative outcomes

Comparative analysis of intraoperative and postoperative outcomes in the CLLAR *versus* RALAR groups is shown before and after propensity score matching in *Table 2*. In the entire cohort before propensity score matching, RALAR showed several

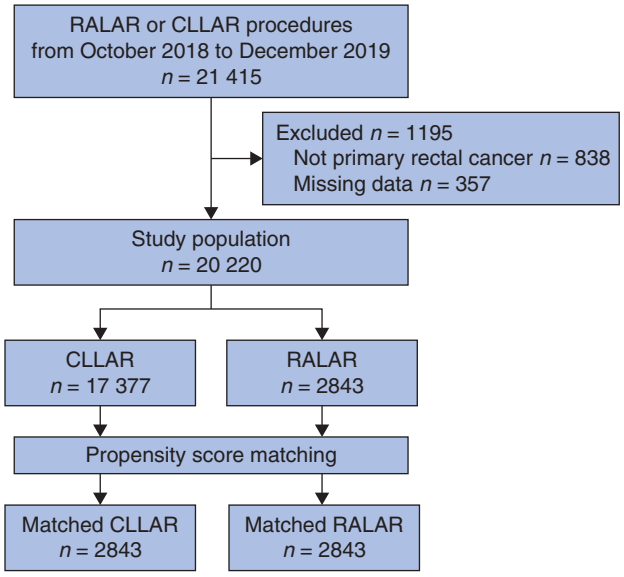

Fig. 1 Study flow chart

CLLAR, conventional laparoscopic low anterior resection; RALAR, robot-assisted low anterior resection.

benefits in terms of clinically significant variables, such as conversion rate to open surgery, intraoperative transfusion, R0 resection rate, mortality (in hospital or within 30 days), overall postoperative overall morbidity, and anastomotic leakage rate. In addition, the RALAR group had decreased intraoperative blood loss, shorter hospital stay, and longer operating time than the CLLAR group.

After propensity score matching, the conversion rate to open surgery was significantly lower in the RALAR group than in the CLLAR group (0.7 *versus* 2.0 per cent; $P < 0.001$). In addition, the RALAR group had a lower in-hospital mortality rate (0.1 *versus* 0.5 per cent; $P = 0.007$), decreased intraoperative blood loss (15 *versus* 20 ml; $P < 0.001$), a shorter hospital stay (13 *versus* 14 days; $P < 0.001$), and a longer duration of operation (352 *versus* 283 min; $P < 0.001$). The CLLAR group had a slightly lower readmission rate within 30 days (2.4 *versus* 3.3 per cent; $P = 0.045$).

Discussion

The conversion rate to open surgery is one of the most widely accepted parameters for evaluating the benefits of RALS, as its technological advantages are thought to overcome the difficulties of laparoscopic surgery and reduce the need for conversion. The ROLARR trial[8], the first and largest RCT of robot-assisted *versus* laparoscopic rectal resection, also set the conversion rate to open surgery as the primary endpoint. Importantly, conversion to open surgery reflects surgical performance and task efficiency, as well as having a significant impact on the patients' clinical course. A recent meta-analysis[9] reported that conversion from CLS to open surgery was associated with an increased risk of anastomotic leakage, overall morbidity, and wound abscess. In addition, several studies have shown that conversion to open surgery is associated with worse long-term outcomes in rectal cancer surgery[10,11]. Therefore, the present findings indicate that RALS is a promising approach for LAR, which may improve short- and long-term outcomes compared with CLS in patients with rectal cancer.

Contrary to the findings reported here, in the ROLARR trial[12] there was no statistical difference in the overall conversion rate to open surgery between RALS and CLS. However, several criticisms were raised against the ROLARR trial; the major issues were insufficient sample size and learning curve effects. First, as the actual conversion rate to open surgery was relatively low compared with the anticipated rate, the number of patients was insufficient to detect statistical differences. Second, the participating surgeons were relatively inexperienced in RALS compared with CLS. Subsequent analysis of the ROLARR trial results showed that RALS had an advantage over CLS in terms of the conversion rate to open surgery when RALS was performed by surgeons who had more RALS experience, regardless of their CLS experience[12]. In addition, in the subgroup analysis of the ROLARR trial, the robot-assisted procedure was associated with a low conversion rate to open surgery in technically demanding situations (men, obese patients, and LAR). A future RCT in an appropriate setting is therefore needed to elucidate the clinical significance of RALS in rectal cancer.

The strengths of this study include the use of an extensive nationwide clinical database that has collected clinical information on over 11 million surgical procedures from more than 5000 facilities registered in Japan[13]. This has been evaluated with respect to reliability of the data collected and verified to be highly accurate in gastrointestinal procedures[6]. Recently, population-based data analyses, such those using the NCD, have gained attention as a study method that enables real-world medical treatment data to be ascertained and appropriate adjustment made for preoperative clinical factors to minimize confounding variables. In terms of conversion rate to open surgery for RALAR, it was affected by several clinical factors, such as sex, co-morbidities, and BMI[14–17]. Therefore, based on the latest nationwide extensive cohort data with background adjustment, the present results provide current real-world evidence regarding perioperative outcomes, including conversion rate to open surgery, of RALAR and CLLAR. Several population-based studies[7,18–22] have reported conversion rates to open surgery for RALAR, ranging from 5 to 9.5 per cent in the USA. Of these, only three studies[7,18,22] conducted propensity matching analysis to compare RALAR with CLLAR. In the present analysis of secondary endpoints, RALAR was also associated with a shorter hospital stay and increased operating time, but not with postoperative morbidity, consistent with a previous population-based comparative study[22]. In terms of decreased in-hospital mortality and reduced intraoperative blood loss in RALAR, controversy remains, as noted in recent systematic reviews and meta-analyses[23,24]. In addition, in the present study, RALS was associated with a slightly increased readmission rate within 30 days, which is not consistent with findings of all previous population-based comparative studies[7,18,22]. In Japan, before national insurance was available for RALAR at each hospital, patients or hospitals took admission costs in the first 10 procedures, and it could be speculated that this Japanese-specific insurance system affected the results. Of note, the literature lacks studies comparing RALAR with CLLAR using a nationwide database from an eastern country. The accumulation of evidence worldwide is, however, essential to demonstrate the actual benefits of robot-assisted rectal surgery.

Another significant finding of this study was that the conversion rate to open surgery for RALAR was low (0.7 per cent) compared with that in previous studies. There are several possible reasons for this favourable outcome. A recent report[25] has shown more significant improvements in surgical techniques, instruments, efficacy, and robotic platforms. In previous studies, the

Table 1 Demographic and clinical characteristics before and after propensity score matching

	Before matching			After matching		
	CLLAR (n = 17 377)	RALAR (n = 2843)	SMD	CLLAR (n = 2843)	RALAR (n = 2843)	SMD
Age (years)						
< 65	5863 (33.7)	1224 (43.1)	0.228	1232 (43.3)	1224 (43.1)	0.023
65 – 75	7163 (41.2)	1126 (39.6)		1142 (40.2)	1126 (39.6)	
> 75	4351 (25.0)	493 (17.3)		469 (16.5)	493 (17.3)	
Women	6031 (34.7)	965 (33.9)	0.016	922 (32.4)	965 (33.9)	0.032
BMI (kg/m^2)						
< 18.5	4252 (24.5)	720 (25.3)	0.055	729 (25.6)	720 (25.3)	0.036
≥ 18.5, < 25.0	11 232 (64.6)	1860 (65.4)		1823 (64.1)	1860 (65.4)	
≥ 25.0	1893 (10.9)	263 (9.3)		291 (10.2)	263 (9.3)	
Any assistance in ADL	562 (3.2)	33 (1.2)	0.142	35 (1.2)	33 (1.2)	0.006
ASA physical status grade						
I	3324 (19.1)	673 (23.7)	0.207	622 (21.9)	673 (23.7)	0.045
II	12 050 (69.3)	1995 (70.2)		2052 (72.2)	1995 (70.2)	
III–V	2003 (11.5)	175 (6.2)		169 (5.9)	175 (6.2)	
Brinkman index						
0	8633 (49.7)	1325 (46.6)	0.071	1300 (45.7)	1325 (46.6)	0.018
< 400	2777 (16.0)	517 (18.2)		527 (18.5)	517 (18.2)	
≥ 400	5967 (34.3)	1001 (35.2)		1016 (35.7)	1001 (35.2)	
Habitual alcohol consumption	9235 (53.1)	1649 (58.0)	0.098	1651 (58.1)	1649 (58.0)	0.001
Chronic steroid use	147 (0.8)	22 (0.8)	0.008	22 (0.8)	22 (0.8)	< 0.001
Weight loss (≥10% within 6 months)	305 (1.8)	45 (1.6)	0.013	44 (1.5)	45 (1.6)	0.003
Hypertension	7042 (40.5)	977 (34.4)	0.128	983 (34.6)	977 (34.4)	0.004
Diabetes mellitus	3422 (19.7)	494 (17.4)	0.060	506 (17.8)	494 (17.4)	0.011
COPD	590 (3.4)	116 (4.1)	0.036	114 (4.0)	116 (4.1)	0.004
Congestive heart failure	80 (0.5)	7 (0.2)	0.036	8 (0.3)	7 (0.2)	0.007
Dialysis	76 (0.4)	16 (0.6)	0.018	17 (0.6)	16 (0.6)	0.005
Ischaemic heart disease*	505 (2.9)	75 (2.6)	0.016	79 (2.8)	75 (2.6)	0.009
Cerebrovascular disease	770 (4.4)	114 (4.0)	0.021	98 (3.4)	114 (4.0)	0.030
Bleeding disorder	484 (2.8)	92 (3.2)	0.026	86 (3.0)	92 (3.2)	0.012
Preoperative transfusion (within 72 h)	144 (0.8)	21 (0.7)	0.010	17 (0.6)	21 (0.7)	0.017
Neoadjuvant chemotherapy†	1316 (7.6)	357 (12.6)	0.166	359 (12.6)	357 (12.6)	0.002
Neoadjuvant radiotherapy†	623 (3.6)	141 (5.0)	0.068	153 (5.4)	141 (5.0)	0.019
Clinical tumour category						
cT0/Tis/T1	3119 (17.9)	661 (23.3)	0.171	685 (24.1)	661 (23.3)	0.026
cT2	3196 (18.4)	594 (20.9)		590 (20.8)	594 (20.9)	
cT3	8441 (48.6)	1249 (43.9)		1219 (42.9)	1249 (43.9)	
cT4	2621 (15.1)	339 (11.9)		349 (12.3)	339 (11.9)	
Clinical node category						
cN0	10 258 (59.0)	1783 (62.7)	0.090	1787 (62.9)	1783 (62.7)	0.010
cN1	4665 (26.8)	734 (25.8)		739 (26.0)	734 (25.8)	
cN2	2454 (14.1)	326 (11.5)		317 (11.2)	326 (11.5)	
Clinical metastasis, cM1	1435 (8.3)	185 (6.5)	0.067	188 (6.6)	185 (6.5)	0.004

Values in parentheses are percentages.*History of myocardial infarction, percutaneous coronary intervention or angina. †Within 90 days. CLLAR, conventional laparoscopic low anterior resection; RALAR, robot-assisted low anterior resection; SMD, standardized mean difference; ADL, activities of daily living; COPD, chronic obstructive pulmonary disease.

conversion rate from RALAR to open surgery decreased in a time-dependent manner, being 9.5 per cent in 2010–2011 and 5 per cent in 2016–2017. Moreover, BMI was low compared with that in the previous study[22].

This study had several limitations. First, the patient cohorts analysed were retrospective in nature and included inherent selection bias. Second, although some biases were adjusted for using propensity score matching, other significant variables such as previous abdominal surgery, the degree of lymph node dissection, and the creation of diverting ostomies, were not. Further study including these clinical variables as confounding factors is needed to evaluate the benefit of RALAR more reliably. In terms of surgical procedure, one reason why inclusion was limited to LAR only was that detailed clinical information had been collected only for LAR among all the rectal procedures in the NCD data set. Therefore, it was not possible to compare RALS with CLS in detail for operations other than LAR. Tumour location is also a critical factor in the study of rectal surgery, which could not be assessed in this study. However, LAR is a standard procedure in Japan, which involves resection of the mesorectum and rectum 3 cm distal from the inferior border of the tumour. As this research focused on LAR only, upper rectal cancers treated by high anterior resection and very low rectal cancers treated by abdominoperineal resection were excluded. Therefore, although missing information about tumour location was a significant limitation of this study, it might not have significantly affected the conversion rate. Third, surgeon experience should be considered when evaluating the conversion rate to open surgery. Unfortunately, surgeons' experience could not have been evaluated appropriately in this study. However, this might not work to the advantage of the RALAR group. As the registration period was the first year that national insurance was available for RALAR and many surgeons had started to perform this operation, a large number of surgeons in the RALAR group were probably in their learning phase for robotic surgery. In contrast, CLLAR was introduced over 20 years ago, and is now widely standardized in Japan. Recently, almost 80

Table 2 Intraoperative and postoperative outcomes

	Before matching			After matching		
	CLLAR (*n* = 17 377)	RALAR (*n* = 2843)	P‡	CLLAR (*n* = 2843)	RALAR (*n* = 2843)	P¶
Primary endpoint						
Conversion to open surgery	480 (2.8)	19 (0.7)	< 0.001	58 (2.0)	19 (0.7)	< 0.001
Intraoperative outcomes						
Duration of operation (min)*	281 (221 – 359)	352 (278 – 444)	< 0.001§	283 (222 – 367)	352 (278 – 444)	< 0.001#
Intraoperative blood loss (ml)*	20 (5 – 74)	15 (3 – 50)	< 0.001§	20 (5 – 75)	15 (3 – 50)	< 0.001#
Intraoperative transfusion	467 (2.7)	38 (1.3)	< 0.001	56 (2.0)	38 (1.3)	0.061
Resection margin status						
R0	16 486 (94.9)	2734 (96.2)	0.010	2713 (95.4)	2734 (96.2)	0.132
R1	216 (1.2)	23 (0.8)		42 (1.5)	23 (0.8)	
R2	675 (3.9)	86 (3.0)		88 (3.1)	86 (3.0)	
Postoperative outcomes						
In-hospital death	67 (0.4)	2 (0.1)	0.005	13 (0.5)	2 (0.1)	0.007
Death within 30 days	49 (0.3)	1 (0.0)	0.007	7 (0.2)	1 (0.0)	0.070
Reoperation within 30 days	1159 (6.7)	168 (5.9)	0.129	178 (6.3)	168 (5.9)	0.580
Readmission within 30 days	494 (2.8)	94 (3.3)	0.173	69 (2.4)	94 (3.3)	0.045
Overall morbidity†						
None	11 911 (68.5)	2023 (71.2)	0.019	1989 (70.0)	2023 (71.2)	0.117
Grade I–II	3642 (21.0)	552 (19.4)		552 (19.4)	552 (19.4)	
Grade III–V	1824 (10.5)	268 (9.4)		302 (10.6)	268 (9.4)	
Superficial incisional SSI	442 (2.5)	89 (3.1)	0.070	75 (2.6)	89 (3.1)	0.268
Deep incisional SSI	165 (0.9)	21 (0.7)	0.275	24 (0.8)	21 (0.7)	0.655
Organ/space SSI	1030 (5.9)	163 (5.7)	0.684	167 (5.9)	163 (5.7)	0.821
Anastomotic leakage	1652 (9.5)	221 (7.8)	0.003	249 (8.8)	221 (7.8)	0.172
Pneumonia	124 (0.7)	14 (0.5)	0.184	13 (0.5)	14 (0.5)	0.847
Pulmonary embolism	19 (0.1)	3 (0.1)	1.000	2 (0.1)	3 (0.1)	1.000
Cardiac arrest	23 (0.1)	2 (0.1)	0.567	8 (0.3)	2 (0.1)	0.109
Cardiac infarction	9 (0.1)	3 (0.1)	0.232	3 (0.1)	3 (0.1)	1.000
Deep vein thrombosis	53 (0.3)	4 (0.1)	0.178	10 (0.4)	4 (0.1)	0.180
Duration of hospital stay (days)*	14 (10–21)	13 (9–18)	< 0.001§	14 (10–20)	13 (9–18)	< 0.001#

Values in parentheses are percentages unless indicated otherwise; *values are median (i.q.r.). †Grade of complications based on Clavien–Dindo classification. CLLAR, conventional laparoscopic low anterior resection; R ALAR, robot-assisted low anterior resection; SSI, surgical-site infection. ‡Pearson's χ^2 test or Fisher's exact test, except §Wilcoxon rank-sum test; ¶McNemar's test or McNemar's exact test, except #Wilcoxon signed-rank test.

per cent of patients with rectal cancer underwent CLS in Japan. Therefore, the results seem to be reliable, as a benefit of RALAR was shown despite the disadvantageous situation for this procedure.

Several advantages of RALAR were identified using the current nationwide database in Japan and propensity score matching analysis. Until further validation in randomized trials in an appropriate setting is available, these data highlight the potential benefit of RALAR in improving the conversion rate to open surgery, in-hospital mortality rate, intraoperative blood loss, and duration of hospital stay for rectal cancer surgery. Although the present results are robust and encouraging, the long-term outcomes, CRM status, urogenital functional outcomes, and cost-effectiveness of RALAR for rectal cancer should be evaluated further.

Funding

Intuitive Surgical Sarl, France, provided financial support. All concerned with the funder had no role in designing and analysing the study or writing the manuscript, except for a scientific review.

Acknowledgements

The authors thank all data managers at hospitals that participated in the NCD project for their efforts in entry of data that were further analysed in this study. This paper reports the results of previous studies with complete analysis plans. The registration can be accessed at https://upload.umin.ac.jp/cgi-open-bin/ctr/ctr_view.cgi?recptno=R000047387. The authors certify that the results of all the registered analyses are reported accordingly. H.E., H.Y., and H.M. are affiliated to the Department of Healthcare Quality Assessment at the University of Tokyo. The department is a social collaboration department supported by grants from the NCD, Johnson & Johnson K.K., and Nipro.

Disclosure. The authors declare no other conflict of interest.

References

1. Gallagher AG, McClure N, McGuigan J, Ritchie K, Sheehy NP. An ergonomic analysis of the fulcrum effect in the acquisition of endoscopic skills. *Endoscopy* 1998;**30**:617–620.
2. Fleshman J, Branda M, Sargent DJ, Boller AM, George V, Abbas M *et al.* Effect of laparoscopic-assisted resection *vs* open resection of stage II or III rectal cancer on pathologic outcomes: the ACOSOG Z6051 randomized clinical trial. *JAMA* 2015;**314**:1346–1355.
3. Stevenson AR, Solomon MJ, Lumley JW, Hewett P, Clouston AD, Gebski VJ *et al.*; ALaCaRT Investigators. Effect of laparoscopic-assisted resection *vs* open resection on pathological outcomes in rectal cancer: the ALaCaRT randomized clinical trial. *JAMA* 2015;**314**:1356–1363.
4. Yamaguchi T, Kinugasa Y, Shiomi A, Kagawa H, Yamakawa Y, Furuatni A *et al.* Short- and long-term outcomes of robotic-

assisted laparoscopic surgery for rectal cancer: results of a single high-volume center in Japan. *Int J Colorectal Dis* 2018;**33**:1755–1762.
5. Yamaguchi T, Kinugasa Y, Shiomi A, Kagawa H, Yamakawa Y, Furutani A *et al.* Oncological outcomes of robotic-assisted laparoscopic *versus* open lateral lymph node dissection for locally advanced low rectal cancer. *Surg Endosc* 2018;**32**:4498–4505.
6. Kanaji S, Takahashi A, Miyata H, Marubashi S, Kakeji Y, Konno H *et al.* Initial verification of data from a clinical database of gastroenterological surgery in Japan. *Surg Today* 2019;**49**:328–333.
7. Hyde LZ, Baser O, Mehendale S, Guo D, Shah M, Kiran RP. Impact of surgical approach on short-term oncological outcomes and recovery following low anterior resection for rectal cancer. *Colorectal Dis* 2019;**21**:932–942.
8. Jayne D, Pigazzi A, Marshall H, Croft J, Corrigan N, Copeland J *et al.* Effect of robotic-assisted *vs* conventional laparoscopic surgery on risk of conversion to open laparotomy among patients undergoing resection for rectal cancer: the ROLARR randomized clinical trial. *JAMA* 2017;**318**:1569–1580.
9. Finochi M, Menahem B, Lebreton G, Lubrano J, Eid Y, Alves A. Are oncological long-term outcomes equal after laproscopic completed and converted laparoscopic converted rectal resection for cancer? *Tech Coloproctol* 2021;**25**:91–99.
10. Jayne DG, Thorpe HC, Copeland J, Quirke P, Brown JM, Guillou PJ. Five-year follow-up of the Medical Research Council CLASICC trial of laparoscopically assisted *versus* open surgery for colorectal cancer. *Br J Surg* 2010;**97**:1638–1645.
11. Parascandola SA, Hota S, Tampo MMT, Sparks AD, Obias V. The impact of conversion to laparotomy in rectal cancer: a National Cancer Database analysis of 57 574 patients. *Am Surg* 2020;**86**:811–818.
12. Corrigan N, Marshall H, Croft J, Copeland J, Jayne D, Brown J. Exploring and adjusting for potential learning effects in ROLARR: a randomised controlled trial comparing robotic-assisted *vs.* standard laparoscopic surgery for rectal cancer resection. *Trials* 2018;**19**:339.
13. Kakeji Y, Takahashi A, Hasegawa H, Ueno H, Eguchi S, Endo I *et al.*; National Clinical Database. Surgical outcomes in gastroenterological surgery in Japan: report of the National Clinical Database 2011–2018. *Ann Gastroenterol Surg* 2020;**4**:250–274.
14. Clancy C, O'Leary DP, Burke JP, Redmond HP, Coffey JC, Kerin MJ *et al.* A meta-analysis to determine the oncological implications of conversion in laparoscopic colorectal cancer surgery. *Colorectal Dis* 2015;**17**:482–490.
15. Crippa J, Grass F, Achilli P, Mathis KL, Kelley SR, Merchea A *et al.* Risk factors for conversion in laparoscopic and robotic rectal cancer surgery. *Br J Surg* 2020;**107**:560–566.
16. da Luz Moreira A, Mor I, Geisler DP, Remzi FH, Kiran RP. Laparoscopic resection for rectal cancer: a case-matched study. *Surg Endosc* 2011;**25**:278–283.
17. Tekkis PP, Senagore AJ, Delaney CP. Conversion rates in laparoscopic colorectal surgery: a predictive model with, 1253 patients. *Surg Endosc* 2005;**19**:47–54.
18. Speicher PJ, Englum BR, Ganapathi AM, Nussbaum DP, Mantyh CR, Migaly J. Robotic low anterior resection for rectal cancer: a national perspective on short-term oncologic outcomes. *Ann Surg* 2015;**262**:1040–1045.
19. Chapman BC, Edgcomb M, Gleisner A, Vogel JD. Outcomes in rectal cancer patients undergoing laparoscopic or robotic low anterior resection compared to open: a propensity-matched analysis of the NCDB (2010–2015). *Surg Endosc* 2020;**34**:4754–4771.
20. Gilmore B, Adam MA, Rhodin K, Turner MC, Ezekian B, Mantyh CR *et al.* Evolution of minimally invasive surgery for rectal cancer: update from the national cancer database. *Surg Endosc* 2021;**35**:275–290.
21. Parascandola SA, Hota S, Sparks AD, Boulos S, Cavallo K, Kim G *et al.* Trends in utilization, conversion rates, and outcomes for minimally invasive approaches to non-metastatic rectal cancer: a national cancer database analysis. *Surg Endosc* 2021;**35**:3154–3165.
22. Hu KY, Wu R, Szabo A, Ridolfi TJ, Ludwig KA, Peterson CY. Laparoscopic *versus* robotic proctectomy outcomes: an ACS-NSQIP analysis. *J Surg Res* 2020;**255**:495–501.
23. Prete FP, Pezzolla A, Prete F, Testini M, Marzaioli R, Patriti A *et al.* Robotic *versus* laparoscopic minimally invasive surgery for rectal cancer: a systematic review and meta-analysis of randomized controlled trials. *Ann Surg* 2018;**267**:1034–1046.
24. Ng KT, Tsia AKV, Chong VYL. Robotic *versus* conventional laparoscopic surgery for colorectal cancer: a systematic review and meta-analysis with trial sequential analysis. *World J Surg* 2019;**43**:1146–1161.
25. Hill A, McCormick J.In experienced hands, does the robotic platform impact operative efficiency? Comparison of the da Vinci Si versus Xi robot in colorectal surgery. *J Robot Surg* 2020;**14**:789–792.