

Learning curve for robotic-assisted surgery for rectal cancer: use of the cumulative sum method

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Abstract

Background Few data are available to assess the learning curve for robotic-assisted surgery for rectal cancer. The aim of the present study was to evaluate the learning curve for robotic-assisted surgery for rectal cancer by a surgeon at a single institute.

Methods From December 2011 to August 2013, a total of 80 consecutive patients who underwent robotic-assisted surgery for rectal cancer performed by the same surgeon were included in this study. The learning curve was analyzed using the cumulative sum method. This method was used for all 80 cases, taking into account operative time.

Results Operative procedures included anterior resections in 6 patients, low anterior resections in 46 patients, intersphincteric resections in 22 patients, and abdominoperineal resections in 6 patients. Lateral lymph node dissection was performed in 28 patients. Median operative time was 280 min (range 135–683 min), and median blood loss was 17 mL (range 0–690 mL). No postoperative complications of Clavien–Dindo classification Grade III or IV were encountered. We arranged operative times and calculated cumulative sum values, allowing differentiation of three phases: phase I, Cases 1–25; phase II, Cases 26–50; and phase III, Cases 51–80.

Conclusions Our data suggested three phases of the learning curve in robotic-assisted surgery for rectal cancer. The first 25 cases formed the learning phase.

Keywords Rectal cancer · Robotic-assisted surgery · Learning curve · CUSUM method · Total mesorectal excision · Lateral lymph node dissection

Some studies have recently been published on the advantages of laparoscopic rectal cancer surgery [1–3]. However, when performing laparoscopic surgery for rectal cancer, positivity of the circumferential resection margins (15.5 %) and conversion rate (33.9 %) were high in a subgroup analysis of the UK Medical Research Council (MRC) trial of conventional versus laparoscopic-assisted surgery in colorectal cancer (CLASICC) [2]. These findings may have been related to the high degree of technical difficulty when performing surgery in the narrow pelvic cavity. Limitations include the use of straight rigid instruments within a narrow working space, limited degrees of freedom, an unstable camera platform with two-dimensional imaging, and poor ergonomics of the instruments.

Since the da Vinci surgical system (Intuitive Surgical, Sunnyvale, CA, USA) was approved by Food and Drug Administration in 2000 and Weber et al. [4] performed the first robotic-assisted colectomy for benign disease in 2001, robotic-assisted surgery has gradually gained popularity. Pigazzi et al. [5] first reported robotic-assisted total mesorectal excision (TME) for rectal cancer in 2006. Some of the advantages gained with robotic-assisted surgery include high-quality three-dimensional imaging, free-moving multi-joint forceps, stable camera work by an operator, use of an image stabilizer, a motion-scaling function, and greatly improved ergonomics [6, 7].

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With the adoption of new techniques, it is important to assess the effects on the surgeon's learning curve. The cumulative sum (CUSUM) method was adopted by the medical profession in the 1970s to analyze learning curves for surgical procedures [8, 9]. Multiple reports on robotic-assisted surgery have been published, but few reports have evaluated the learning curve for robotic-assisted surgery for rectal cancer [10–15]. Three reports using the CUSUM method have suggested that the learning curve phase is achieved after 15–35 cases [11, 12, 14]. On the other hand, previous studies have suggested a wide ranging minimum requirement of 40–90 cases to reach the first stabilization of laparoscopic surgery for rectal cancer [16–20]. Robotic-assisted surgery offers technical advantages over laparoscopic surgery and thus may shorten the learning curve compared with laparoscopic surgery.

The present study attempted to evaluate the learning curve in robotic-assisted surgery for rectal cancer based on 80 consecutive cases treated by a single surgeon at a single institute. In Japan, TME with lateral lymph node dissection (LLD) has been the standard treatment for patients with lower rectal cancer [21]. We believe that our series represents the first to specifically analyze the learning curve in robotic-assisted surgery for rectal cancer, including LLD.

Materials and methods

Patients and study design

From December 2011 to August 2013, a total of 125 patients underwent robotic-assisted surgery for rectal cancer at Shizuoka Cancer Center Hospital. These patients comprised the first participants in our team's experience with robotic-assisted surgery. Of these, 80 consecutive patients who underwent robotic-assisted surgery by an expert surgeon (Y.K.) for rectal cancer were included in this study. The rest of the robotic surgical team consisted of robotic surgeons (T.Y. and A.S.) who performed the surgeries for the remaining 45 patients with rectal cancer, an assistant surgeon (H.K.), nurses, and the anesthetic team, all of whom were familiar with the robot setup.

We extracted data from our prospectively maintained colorectal database, which contains information regarding patient demographics, preoperative assessment, operative characteristics, operative time (OT), surgeon console time (SCT), morbidity, pathological characteristics, adjuvant therapy, and follow-up. Indications for LLD were lower rectal cancer with T3–4, or T1–2 rectal cancer with metastasis to lateral lymph nodes, as described by the Japanese Society for Cancer of the Colon and Rectum (JSCCR) guidelines for the treatment of colorectal cancer [22]. Until December 2011, rectal cancer surgeries with

LLD or with direct invasion to other organs were performed using the open method, while the remaining rectal cancer surgeries were performed using a laparoscopic method. Patients with obvious suspicion of direct invasion to other organs underwent neoadjuvant chemoradiotherapy with TME. Patients were staged using the tumor node metastasis (TNM) classification [23]. All study protocols were approved by our institutional review board (25-J100-25-1-3).

Operative technique

All procedures were performed using a systematic approach that included colonic and pelvic phases by a robotic approach. During the colonic phase, the inferior mesenteric artery and vein were ligated under a medial-to-lateral approach. When required, the splenic flexure was taken down. The pelvic phase involved sharp dissection of the prehypogastric nerve fascia and behind Denonvilliers' fascia to avoid autonomic nerve injury during TME for lower rectal cancer [24]. Total OT was defined as the interval from first incision to closure of the incisions. SCT was the actual time the surgeon spent at the robotic console during the procedure, which directly corresponded to the robotic portion of the procedure.

CUSUM method

The learning curve was analyzed using the CUSUM method similar to that described by Bokhari et al. [12]. The CUSUM was the running total of differences between the individual data points and the mean of all data points. This method was used for all 80 cases, taking into account the OT ($CUSUM_{OT}$). Patients were chronologically arranged from the earliest to latest data of surgery. The $CUSUM_{OT}$ for the first case was the difference between the OT for the first case and the mean OT for all cases. The $CUSUM_{OT}$ of the second case was the $CUSUM_{OT}$ of the previous case added to the difference between the OT of the second case and the mean OT for all cases. This same procedure was repeated for each patient except for the last case, which was calculated as zero. We also performed linear regression analysis and detected the sign of the slope of regression.

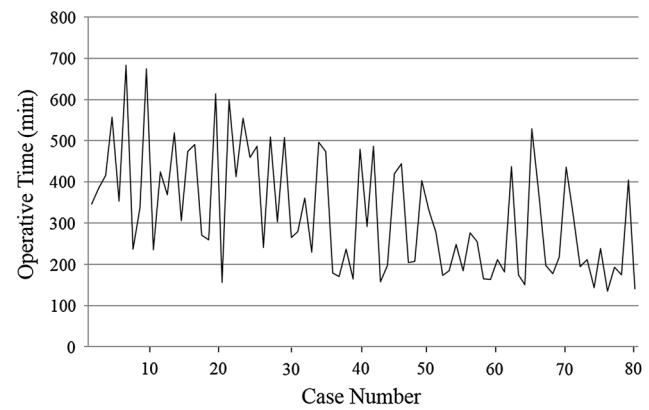
Statistical analysis

All statistical analyses were performed using IBM SPSS Statistics for Windows version 19 software (SPSS, an IBM company, Chicago, IL, USA) and R version 3.0.1 (R Foundation for Statistical Computing). Fisher's exact test or the Wilcoxon rank-sum test was used for comparisons of two groups. Data differences between groups were considered statistically significant at the level of $p < 0.05$.

Table 1 Demographic and perioperative characteristics and TNM staging of our patient cohort ($n = 80$)

Parameters	Number
Age (years) [median (range)]	63 (36–82)
Sex	
Male	53 (66.3 %)
Female	27 (33.8 %)
BMI (kg/m ²) [median (range)]	22.9 (16.7–29.5)
ASA grading	
Grade 1	28 (35.0 %)
Grade 2	52 (65.0 %)
Grade 3	0 (0 %)
Tumor location	
Upper rectum	13 (16.3 %)
Mid rectum	12 (15.0 %)
Lower rectum	55 (68.8 %)
Tumor size (cm) [median (range)]	3.8 (0.8–16.0)
Neoadjuvant chemoradiotherapy	2 (2.5 %)
Type of operation	
Anterior resection	6 (7.5 %)
Low anterior resection	46 (57.5 %)
Intersphincteric resection	22 (27.5 %)
Abdominoperineal resection	6 (7.5 %)
Lateral lymph node dissection	28 (35.0 %)
Conversion	0 (0 %)
Operative time (min) [median (range)]	280 (135–683)
Surgeon console time (min) [median (range)]	180 (55–550)
Blood loss (ml) [median (range)]	17 (0–690)
pT	
Tis	2 (2.5 %)
T1	24 (30.0 %)
T2	18 (22.5 %)
T3	31 (38.8 %)
T4	5 (6.3 %)
pN	
N0	47 (58.8 %)
N1	24 (30.0 %)
N2	9 (11.3 %)
pStage	
0	2 (2.5 %)
I	29 (36.3 %)
II	16 (20.0 %)
III	29 (36.3 %)
IV	4 (5.0 %)
Lymph node harvest [median (range)]	35 (11–112)
Distal margin (cm) [median (range)]	2.3 (0.3–9.5)
R1 resection	0 (0 %)

Values in parentheses represent percentages unless otherwise noted

**Fig. 1** Graph of raw operative times plotted for each of the 80 consecutive patients

Results

Table 1 summarizes the demographic and perioperative characteristics and TNM staging of the 80 consecutive patients who underwent robotic-assisted surgery for rectal cancer. Two patients with suspected direct invasion to the prostate underwent neoadjuvant chemoradiotherapy. Operative procedures included anterior resection (AR) in 6 patients, low anterior resection (LAR) in 46 patients, intersphincteric resection (ISR) in 22 patients, and abdominoperineal resection (APR) in 6 patients. LLD was performed in 28 patients (35.0 %). Median OT was 280 min (range 135–683 min), and median SCT was 180 min (range 55–550 min). Median blood loss was 17 mL (range 0–690 mL), and none of the patients received intraoperative blood transfusion. No operations were converted to laparotomy.

A graph of raw OTs plotted in each of the cases arranged in chronological order is shown in Fig. 1. Once OTs were arranged, we calculated CUSUM_{OT} values for each of the cases to obtain the graph of the learning curve (Fig. 2). We were able to differentiate three phases in the graph: phase I, Cases 1–25; phase II, Cases 26–50; and phase III, Cases 51–80. Figure 3 shows the lines of best fit for the three phases of the learning curve.

Comparative analysis of the demographic characteristics, perioperative characteristics, and TNM staging is shown in Table 2. In terms of the demographic characteristics, significantly older cases were seen in phase I in comparison with phases II and III combined ($p = 0.02$). Other demographic characteristics and TNM staging did not differ significantly between phase I and phases II and III combined. No significant differences in type of operation were seen between phase I and phases II and III

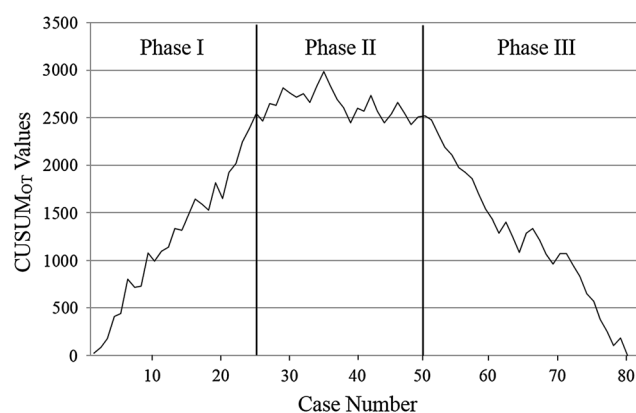


Fig. 2 The three phases of operative time in terms of the CUSUM learning curve

combined, but the proportion of LLD cases differed significantly ($p = 0.04$). The OT of phases II and III combined was significantly shorter than that of phase I ($p = 0.0001$). Blood loss in phases II and III combined was significantly less than that in phase I ($p = 0.001$).

Postoperative data are presented in Table 3. No cases showed Clavien–Dindo classification of morbidity Grade III or IV. The frequency of Clavien–Dindo classification of morbidity Grade II–IV did not differ between phase I and phases II and III combined. Postoperative hospital stay was significantly shorter in phases II and III combined than in phase I ($p = 0.02$).

Discussion

When adopting a new device like the da Vinci surgical system, proficiency and competence must be achieved. McCulloch et al. [25] suggested that to improve the standards of clinical research in surgery, learning curves and variations in the techniques and quality of surgery must be measured and controlled continuously. The CUSUM technique has been employed by the medical profession to analyze learning curves for surgical procedures since the 1970s [8, 9]. The CUSUM method has been used to evaluate a practitioner's initial and continued successful performance of procedures. The main advantages of this approach are the independence from the sample size, the effectiveness in detecting small shifts in the system, and the ability to allow continuous analysis in time and rapid evaluation of data. The CUSUM method has thus been used as an indicator of satisfactory outcomes in relation to the acquisition of clinical skills [11].

To date, only three studies in terms of robotic-assisted surgery for rectal cancer have reported analysis of the learning curve using the CUSUM method [11, 12, 14]. Two of those three studies focused on rectal cancer surgery [11,

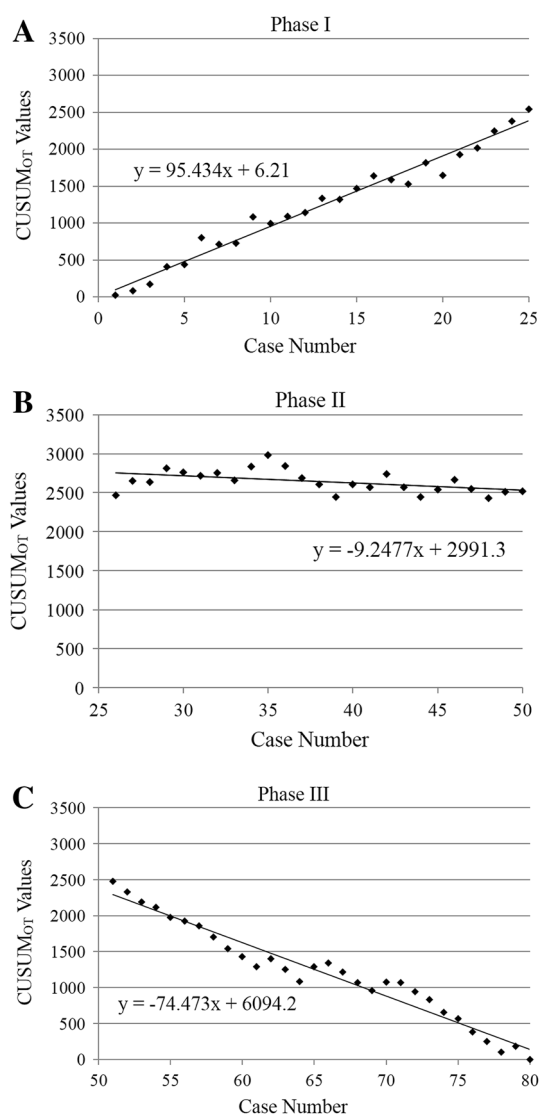


Fig. 3 Lines of best fit for three phases of the CUSUM learning curve. **A** Phase I shows the initial learning phase. **B** Phase II shows the stabilization of operative time. **C** Phase III shows the experienced phase

14], but the remaining study analyzed both benign and malignant colorectal diseases [12]. Jimenez-Rodriguez et al. [11] included 43 rectal cancer cases and analyzed the learning curve using the CUSUM method. They concluded that the learning curve for robotic-assisted surgery for rectal cancer may be divided into an initial phase of skills acquisition, a second phase of consolidation of the technique, and a third phase when the surgeon masters the technique and deals with more complex cases. According to their study, the estimated learning phase for rectal cancer was achieved after 21–23 cases. Similarly, Sng et al. [14] reported that at least three phases were present in the learning curve of 197 robotic-assisted surgeries for rectal cancer patients using the CUSUM method. The first phase,

Table 2 Comparative study of the three phases according to demographic and perioperative characteristics and TNM staging

	Phase I (<i>n</i> = 25)	Phase II (<i>n</i> = 25)	Phase III (<i>n</i> = 30)	<i>p</i> Phase I vs. II + III
Age (years) [median (range)]	66 (36–79)	59 (39–72)	63 (49–82)	0.02
Sex				
Male	15	17	21	
Female	10	8	9	0.45
BMI (kg/m ²) [median (range)]	22.6 (18.3–28.0)	23.9 (16.7–29.5)	23.5 (17.6–29.4)	0.43
ASA grading				
Grade 1	7	8	13	
Grade 2	18	17	17	
Grade 3	0	0	0	0.45
Tumor location				
Upper rectum	2	3	8	
Mid rectum	4	6	2	
Lower rectum	19	16	20	0.50
Tumor size (cm) [median (range)]	4.0 (1.0–16.0)	4.0 (1.2–9.7)	3.2 (0.8–11.4)	0.31
Neoadjuvant chemoradiotherapy	0	2	0	1.00
Type of operation				
Anterior resection	1	2	3	
Low anterior resection	13	15	18	
Intersphincteric resection	9	7	6	
Abdominoperineal resection	2	1	3	0.63
Lateral lymph node dissection	13	10	5	0.04
Operative time (min) [median (range)]	415 (156–683)	292 (157–509)	196 (135–529)	0.0001
Blood loss (ml) [median (range)]	30 (5–690)	15 (0–63)	7 (0–318)	0.001
pT				
Tis	1	1	0	
T1	9	4	11	
T2	5	7	6	
T3	9	12	10	
T4	1	1	3	0.87
pN				
N0	14	14	19	
N1	8	8	8	
N2	3	3	3	0.95
pStage				
0	1	1	0	
I	8	7	14	
II	5	6	5	
III	10	11	8	
IV	1	0	3	0.95
Lymph node harvest [median (range)]	35 (11–112)	37 (15–60)	32 (14–75)	0.89
Distal margin (cm) [median (range)]	1.6 (0.5–6.9)	2.2 (0.3–5.6)	3.1 (0.5–9.5)	0.24

consisting of 35 cases, represented the initial learning curve. Those results were consistent with our own analysis, which showed three well-differentiated phases. Phase I (Cases 1–25) represents the initial learning phase. Phase II (Cases 26–50) shows stabilization of OT, and phase III (Cases 51–80) represents the experienced phase.

On the other hand, previous studies have suggested long training periods of 40–90 cases as the estimated number needed to complete the learning curve in laparoscopic surgery for rectal cancer [16–20]. Son et al. [19] concluded that to attain proficiency in laparoscopic surgery for rectal cancer, the surgical learning curve should entail a minimum of

Table 3 Comparative study of the three phases according to complications and postoperative hospital stay

	Phase I (<i>n</i> = 25)	Phase II (<i>n</i> = 25)	Phase III (<i>n</i> = 30)	<i>p</i> Phase I vs. II + III
Clavien–Dindo classification				
Grade 0–I	22	23	27	
Grade II–IV ^a	3	2	3	0.70
Complications ^b				
Wound infection	0	0	1	1.00
Small bowel obstruction	0	0	0	–
Anastomotic leakage	0	0	0	–
Urinary retention	2	0	0	0.10
Urinary infection	0	1	0	1.00
Enteritis	0	1	1	1.00
Catheter-related infection	1	0	0	0.31
Pneumonia	0	0	1	1.00
Postoperative hospital stay (days) [median (range)]	8 (7–12)	7 (6–12)	7 (6–15)	0.02

^a There were no cases of Clavien–Dindo classification of morbidity Grades III or IV

^b Clavien–Dindo classification of morbidity, Grade II–IV

60–80 cases with multidimensional analysis using the CUSUM method. Bege et al. [16] suggested that the learning process for laparoscopic mesorectal excision affects the first 50 cases mostly heavily in terms of postoperative complications, but does not adversely affect oncological results using the moving average and the CUSUM method. Laparoscopic surgery for rectal cancer might be technically difficult when performing surgery in the narrow pelvic cavity. These limitations include the use of straight rigid instruments within a narrow working space, limited degrees of freedom, an unstable camera platform with two-dimensional imaging, and poor ergonomics of instruments. Robotic-assisted surgery offers technical advantages such as high-quality three-dimensional imaging, free-moving multi-joint forceps, and image stabilization over laparoscopic surgery and thus may shorten the learning curve compared with laparoscopic surgery.

We believe that our series is the first to specifically analyze the learning curve for robotic-assisted surgery for rectal cancer including LLD. A retrospective analysis conducted in Japan reported that lateral lymph node metastasis was present in 15.6–20.4 % of patients with lower rectal cancer [21], so TME with LLD has been utilized as a standard treatment for patients with lower rectal cancer, as described by the JSCCR guidelines [22]. In terms of open mesorectal excision with LLD, Fujita et al. [26] reported the short-term

results of mesorectal excision with and without LLD for clinical stage II or III lower rectal cancer. OT was significantly longer in the mesorectal excision with LLD group (median, 360 min; interquartile range (IQR), 296–429 min) than in the mesorectal excision alone group (median, 254 min; IQR, 210–307 min, $p < 0.0001$). Reports of laparoscopic TME with LLD are rare. Liang et al. [27] indicated that laparoscopic TME with LLD was technically difficult to perform, so laparoscopic LLD should be limited to some selected patients. The main reasons why the procedure for open or laparoscopic LLD remains difficult are that the operative field of the pelvic side wall is small and the anatomy is complex. However, our case series included 28 patients (35.0 %) who underwent robotic-assisted LLD, and the procedure was relatively safe and feasible because no patients showed Clavien–Dindo classification of morbidity Grades III–IV and no operations were converted to laparotomy. Robotic-assisted surgery offers technical advantages such as free-moving multi-joint forceps and precise dissection can be achieved early on, so the initial learning phase of our cases was similar to previous reports [11, 14].

Previous reports have described a trend of experienced surgeons tending to include increasingly more difficult cases toward the later part of their case series [11, 12, 14]. In contrast, our initial learning phase of 25 cases included LLD in 13 cases (52.0 %), while phases II and III combined consisted of 55 cases, including LLD in 15 cases (27.3 %, $p = 0.04$). Our study thus differed from previous reports in that our series included more frequently challenging cases in the earlier part of the series and we may not encounter a phase including more complex cases in the future. Our initial learning phase only comprised 25 cases; therefore, we consider that the technical difficulties of each case did not influence the learning curve.

Several limitations need to be considered for this study. First, an expert laparoscopic surgeon (Y.K.) performed robotic-assisted surgery. At the point of commencing robotic-assisted surgery, he had performed over 500 laparoscopic colorectal resections, including more than 200 for rectal cancer. He was well-informed about pelvic anatomy and laparoscopic technique. Our results therefore may not be applicable to surgeons without this level of skill in laparoscopic techniques. However, the shorter learning curve may be attributed to the robotic system with advanced technology, because we had little experience in performing laparoscopic rectal cancer surgery with LLD at the point of commencing robotic-assisted surgery. A second limitation was that we did not analyze long-term oncological and functional outcomes, such as voiding and sexual functions. A randomized controlled trial is necessary to establish the true benefits of robotic-assisted surgery for rectal cancer compared with open and laparoscopic surgery.

Conclusions

Our study, using the CUSUM method, identified three phases of the learning curve in robotic-assisted surgery for rectal cancer. The data suggested that the initial 25 cases formed the learning phase, the second 25 cases formed the plateau phase, and the last 30 cases comprised the experienced phase. The learning curve for robotic-assisted surgery may shorten that of laparoscopic surgery. These results may impact the setting of ongoing and future trials.

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