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ORIGINAL ARTICLE

Learning curve analysis for prophylactic bilateral robot-assisted lateral lymph node dissection for lower rectal cancer: a retrospective study

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Abstract

Background Lateral lymph node dissection (LLND) is an important surgical procedure in the treatment of lower rectal cancer (RC). However, limited data are available regarding the learning curve for robot-assisted LLND (RA-LLND). This study aimed to evaluate the learning curve for prophylactic bilateral RA-LLND for lower RC.

Methods We retrospectively analyzed 58 consecutive patients with clinical stage II/III lower RC who had undergone prophylactic bilateral RA-LLND between July 2020 and June 2024. Cumulative sum (CUSUM) analysis was used to evaluate the learning curve for bilateral RA-LLND operative time.

Results The mean age of patients was 61.5 years, and mean body mass index was 23.4 kg/m^2. The proportion of neoadjuvant therapy was 8.6%. Mean prophylactic bilateral RA-LLND operative time was 173.7 min. CUSUM analysis divided the learning curve for prophylactic bilateral RA-LLND operative time into three phases: initial learning phase (20 cases); competence phase (16 cases); and master/proficiency phase (subsequent cases). Mastery of surgical technique was achieved after performing the 36th case. Comparisons of surgical outcomes in terms of operative parameters and complications were made between phases 1 and 2 combined and phase 3. A significant reduction in mean prophylactic bilateral RA-LLND operative time was observed between phases 1 and 2 compared with phase 3 ($P < 0.01$). Mean blood loss was decreased in phase 3 (40.5 ml) compared to phases 1 and 2 combined (148.2 ml, $P < 0.01$). The frequencies of overall postoperative complications directly related to LLND and urinary dysfunction were significantly reduced in phase 3 compared to phases 1 and 2 combined ($P = 0.04$, and $P = 0.02$, respectively).

Conclusions The three phases identified by CUSUM analysis represented characteristics of the learning curve for prophylactic bilateral RA-LLND. These data suggest that 20 cases are required for the early stage of the learning curve, whereas mastery level could be achieved after 36 cases.

Keywords Robotic surgery · Rectal cancer · Learning curve · CUSUM methodology · Lateral pelvic lymph node dissection

Background

Rectal cancer (RC) accounts for 38.9% of the total incidence of colorectal cancer (CRC), and 729,833 new cases were reported worldwide in 2022 [1]. Total mesorectal excision (TME) is widely accepted as the international standard for the surgical treatment of RC and reduces the risk of local recurrence (LR). However, TME alone might be insufficient to prevent LRs such as lateral lymph node (LLN) recurrence. In Japan, the Japanese Clinical Oncology Group 0212 [2] suggested the oncological benefit of LLN dissection (LLND) for reducing LR of lower RC. In Western countries, on the other hand, neoadjuvant radiotherapy (RT) or chemoradiotherapy (nCRT) and total neoadjuvant therapy (TNT) in combination with TME are considered essential in the treatment strategy for lower RC [3–5]. However, recent studies have reported that nCRT/TNT is insufficient to prevent LR and that the area of the lateral pelvis is the main region at risk of LR. Interest in strategies for LLN treatment has

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been moving toward performing LLND in both Eastern and Western countries [6–9].

Recently, robotic surgery has been rapidly gaining popularity for the treatment of patients with RC because of the advantages of using multi-joint forceps with motion scaling, high-quality 3-dimensional cameras, and greatly improved ergonomics [8]. Robot-assisted LLND (RA-LLND) was first described by Park et al., who described a series of eight patients [10]. Theoretically, the robotic approach may be ideally suited to the performance of LLND by facilitating the precise dissection of lymph nodes (LNs) from complicated neurovascular structures within the narrow pelvic cavity owing to the inherent advantages of robotic procedures. Several recent studies have reported favorable outcomes in terms of clinical benefits from RA-LLND [11–14].

Surgical proficiency keeps improving with ongoing innovations in surgical instrumentation and technology. The development of every new surgical method or tool comes with a period of acquisition required to attain surgical proficiency. This period allows the surgeon to become increasingly familiar with the fine details of the robotic technique, allowing safe and efficient surgical procedures even when dealing with extremely complex anatomy. The method for predicting surgical proficiency is known as the surgical learning curve, usually defined by the number of cases required to achieve proficiency. Cumulative sum (CUSUM) analysis transforms raw data into the running total of data deviations from the group mean, enabling investigators to visualize data for trends not discernable using other approaches. CUSUM analysis is frequently used to assess the learning curve in physicians as an indicator of satisfactory outcomes during the acquisition of clinical skills [15, 16]. According to a previous study, the number of cases required to attain proficiency in laparoscopic and robotic colorectal resection ranges widely [17].

LLND is technically challenging, but is considered vitally important for colorectal surgeons to develop the skills necessary for LLND as an alternative or supplement to nCRT/TNT. Multiple reports on learning curves for robotic surgery have been published, but limited data are available regarding the learning curve for RA-LLND using CUSUM analysis [18–20]. We aimed to analyze the learning curve for prophylactic bilateral RA-LLND using CUSUM methodology.

Methods

Study design

This single-center, retrospective study investigated the learning curve for RA-LLND. Between July 2020 and June 2024, we retrospectively analyzed 58 consecutive patients who had undergone prophylactic bilateral RA-LLND for clinical stage II/III lower RC at Osaka International Cancer Institute, Japan. This retrospective study was approved by the institutional review board (approval no. 18033). All patients were thoroughly informed about the surgical procedure and provided written informed consent.

Data sources

Data used in the study were obtained from the medical records at our hospital. All recorded clinical and pathological data were revalidated according to the medical and pathology records. The following demographic data were collected: sex, age, body mass index (BMI), antiplatelet/coagulant use, previous abdominal surgery, preoperative carcinoembryonic antigen (CEA) level, preoperative carbohydrate antigen (CA)19-9 level, distance from the anal verge, clinical and pathological TNM stages according to the 8th edition of the UICC classification [21], preoperative chemotherapy, type of surgery, length of postsurgical stay, tumor size, histology, and lymphovascular invasion (LVI). No data were missing for any of the examined variables.

Surgical techniques and postoperative complications

RA-LLND in this study was performed by three certified surgeons using the da Vinci Xi Surgical System (Intuitive Surgical Inc., Sunnyvale, CA). Under general anesthesia, five ports are implanted in the abdominal region, centered around a camera port in the umbilical region (Fig. 1a). Once the RC was resected, LLND was performed in two phases: the first phase comprised internal iliac lymph nodes (#263LNs), and the second phase comprised obturator LNs (#283LNs). First, the ureter was identified and mobilized. The lateral surface of the pelvic plexus was separated so that the autonomic nerve system, including the hypogastric nerve, pelvic splanchnic nerves, and pelvic plexus, formed one plane. This plane was taken as the medial border of the internal LN dissection. The internal iliac LNs were dissected from the internal iliac region present between the ureterohypogastric nerve fascia [22] and vesicohypogastric fascia [23] (Fig. 1b). The inferior vesical vessels are spared, in principle to avoid urinary dysfunction and prioritize blood supply to the bladder. Next, the bifurcation of the internal and external iliac arteries was dissected, later forming the proximal boundary of the internal iliac LN dissection plane. The obturator LNs were then dissected from the lateral side of the internal iliac vessels and further along the obturator foramen and Alcock's canal distally, the external iliac vessels and obturator internus laterally, and the sacral nerve and coccygeus muscle posteriorly (Fig. 1c). The obturator nerve

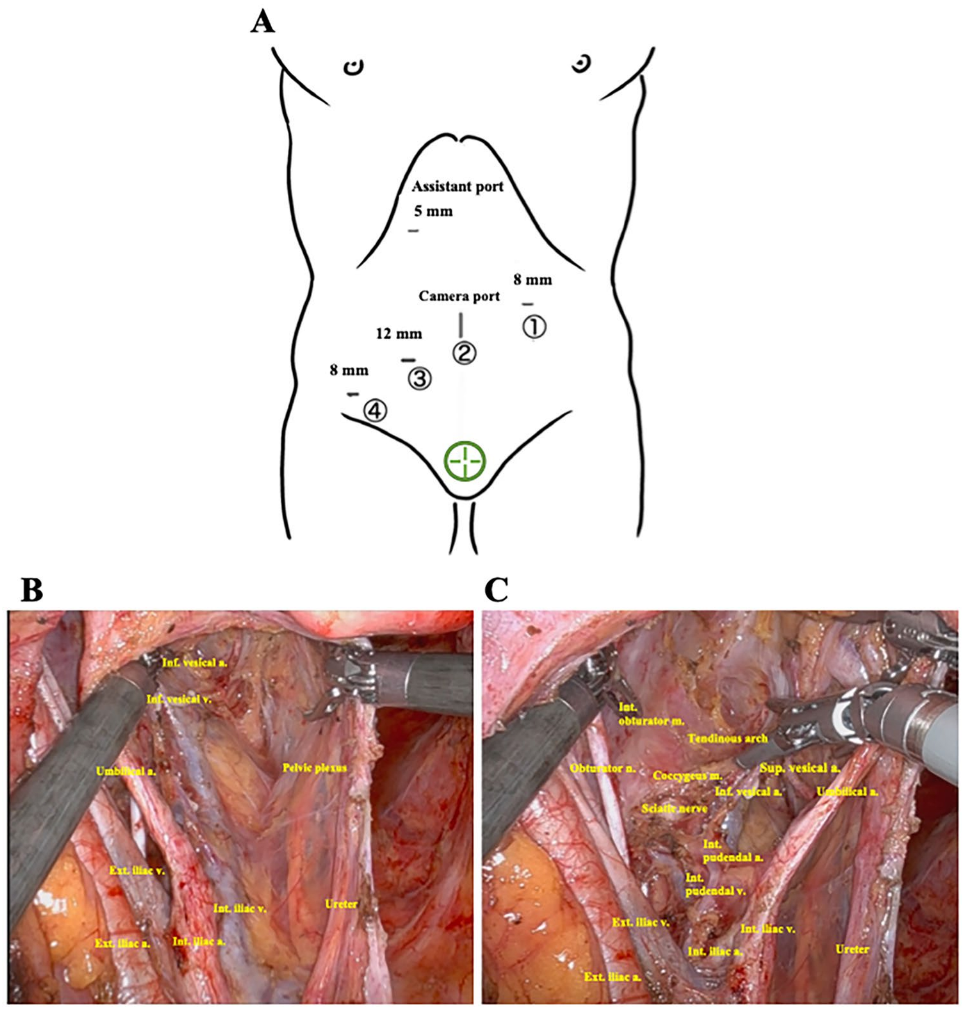

Fig. 1 **a** Surgical port position. **b**, **c** Surgical view of left lateral area after lateral lymph node dissection, showing the internal iliac lymph node area (**b**) and obturator lymph node area (**c**)

was preserved and the obturator artery and vein were dissected. Lymphatic adipose tissue was collected in a sterile specimen bag and extracted.

Postoperative complications and mortality were defined as events occurring during the postoperative hospital stay or within 30 days after surgery. Postoperative complications were categorized according to the Clavien–Dindo (CD) classification [24]. Postoperative urinary dysfunction was evaluated by the measurement of residual urine volume. The residual urine volume was measured by catheterization or ultrasound after Foley catheter removal. We estimated postoperative urinary dysfunction according to the protocol defined in the Japanese Clinical Oncology Group 0212 [25]. A residual urine measurement was counted as one time when the sum of any discharged urinary volume and any residual urinary volume was greater than 150 ml. When the urine volume measurement was performed three times, urinary dysfunction was defined as the presence of 50 ml residual urine on at least one occasion. When the urine measurement was performed two times, urinary dysfunction was defined as the presence of 50 ml residual urine or a clinical diagnosis of urinary dysfunction [25]. All such events were assessed by a clinician and documented in the database.

Design considerations for potential learning effects

In order to minimize confounding due to learning effects, a surgeon inclusion criterion mandating a minimum level of experience in surgical technique was included. The aim of this was to ensure that all participating surgeons have experience in both a surgical approach (robotic) and a specific technique (LLND). In the present study, participating surgeons had performed a minimum of 5 open or laparoscopic LLND and at least 40 robotic RC resections before taking part in this study.

RA-LLND cases in this study are the first RA-LLND cases of the participating surgeons. All participating surgeons have never performed RA-LLND in the past. The same surgeon performed bilateral RA-LLND.

Cumulative sum analysis

CUSUM analysis was performed to evaluate operative times as cases progressed chronologically. LLND operative times were calculated from the start of LLND on one side to the end of LLND on the other side and plotted on a line graph to be used in CUSUM analysis. CUSUM represents a running total of differences between each consecutive data point and the overall mean operative time. CUSUM for the first case is equal to the LLND operative time minus the overall mean LLND operative time. CUSUM for all subsequent cases follows the following equation: $CUSUM_n = CUSUM_{n-1} + (\text{operative time}_n - \text{operative time}_{\text{mean}})$, where n represents the number of operation cases.

The CUSUM graph was expressed using a line chart in Excel 2016 (Microsoft, Redmond, WA, USA). The trend of learning outcomes was confirmed through the slope of the CUSUM curve.

Statistical analysis

Data are presented as mean ± standard deviation for continuous variables and as the number and percentage for categorical variables. The χ^2 test was used for comparisons of categorical variables. Continuous variables were compared using the Mann–Whitney test. All statistical analyses were performed using JMP Pro version 17 (SAS Institute, Cary, NC, USA). Values of $P < 0.05$ were considered to indicate statistical significance.

Results

Patient characteristics

A total of 58 patients were evaluated for inclusion, all of whom underwent bilateral prophylactic RA-LLND for lower RC. The baseline characteristics of patients are provided in Table 1. The average age of patients was 61.5 years, with an average BMI of 23.4 kg/m^2. The 58 patients comprised 39 men (67.2%) and 19 women (32.8%). Mean distance between the tumor and anal verge was 4.3 cm. The rate of neoadjuvant chemotherapy was 8.6%. By TNM stage, the rate of clinical stage III was 56.9%. Mean bilateral RA-LLND operative time was 173.7 min, and mean blood loss was 107.4 ml. The overall rate of operative complications was 25.8%, while complications directly related to LLND showed a rate of 13.7%. The mean number of LNs harvested was 33.8, and the mean number of LLNs was 17.3. The number of LLN metastases (LLNMs) was 11 (19.0%).

Table 1 Baseline characteristics among overall cohort

	Total (*N* = 58)
Sex	
Male	39 (67.2)
Female	19 (32.8)
Age, years	61.5 ± 9.7
BMI, kg/m^2	23.4 (0.6)
Distance from tumor to anal verge, cm	4.3 ± 1.9
Neoadjuvant chemotherapy	5 (8.6)
Clinical TNM stage	5 (8.6)
II	25 ± 43.1
III	33 ± 56.9
Estimated bilateral LLND operative time, min	173.7 ± 26.3
Estimated blood loss, ml	107.4 ± 150.3
Intraoperative complication	0 (0.0)
Conversion	0 (0.0)
Overall complications	15 (25.8)
Complications directly related to LLND	8 (13.7)
Severe complications (CD classification ≥ III)	4 (6.9)
Length of postsurgical stay, days	14.6 ± 7.5
Number of LLNs harvested	17.3 ± 6.5
Number of #263 LNs harvested	3.3 ± 2.9
Number of #283 LNs harvested	13.9 ± 6
Number of LLN metastases	11 (19.0)

Values are given as number (percentage) or mean ± standard deviation

BMI body mass index, *LLND* lateral lymph node dissection, *CD* Clavien–Dindo classification, *LLN* lateral lymph node *LN* lymph node

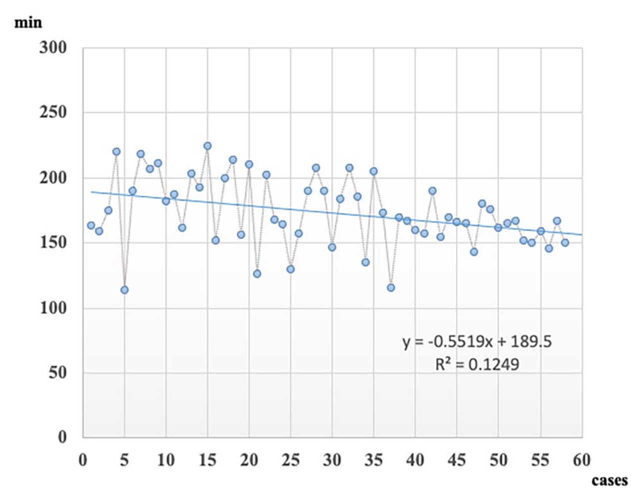

Fig. 2 Mean prophylactic bilateral robot-assisted lateral lymph node dissection operative time plotted against number of cases

Learning curve analysis using CUSUM methodology

Figure 2 shows the mean prophylactic bilateral RA-LLND operative time plotted against case number. Supplementary

Fig. 1 shows the mean prophylactic bilateral RA-LLND operative time plotted against case number according to each surgeon. The negative slope indicates that bilateral RA-LLND operative time decreased as the number of cases increased. Figure 3 shows CUSUM curves for bilateral RA-LLND. The slope ascends from the first case to the 20th, then flattens out between the 21st and 36th cases. From the 37th case, the curve had a tendency to decline overall. We classified three phases based on those slope changes. Cases 1–20 were defined as phase 1 (learning phase), indicating that the operative time was still longer than the average. Cases 21–36 were defined as phase 2 (competence phase), indicating that the operative time was almost equal to the average; and the 37th–58th cases were defined as phase 3 (master/proficiency phase), suggesting that the operative time was shorter than the average.

Patient characteristics and perioperative outcomes in the three learning phases

Next, we compared outcomes between phases 1 and 2 combined (learning/competence phase) and phase 3 (mastery/proficiency phase). Comparisons of various parameters between the two phases identified by CUSUM analysis are presented in Tables 2, 3, 4, and 5. Table 2 lists the patient baseline characteristics. Age, sex, BMI, the history of antithrombotic therapy or prior abdominal surgery, serum CEA or CA19-9 value, tumor distance from anal verge, the rate of neoadjuvant chemotherapy, and clinical TNM stage were not significantly different between phases 1 and 2 combined and phase 3.

Comparisons of intraoperative parameters are presented in Table 3. No intraoperative complications were encountered in any group and no patients required intraoperative blood transfusion. Mean bilateral RA-LLND operative time in phase 3 (160.5 min) was significantly shorter than in phases 1 and 2 (180.9 min, $P < 0.01$). Mean blood loss was significantly decreased in phase 3 (40.5 ml) than in the first two phases (148.2 ml, $P < 0.01$). No significant differences were seen in terms of type of procedure, total operative time, rate of autonomic nerve preservation, or length of postsurgical stay between phases 1 and 2 combined and phase 3. No conversions to an open or laparoscopic approach were required in any group.

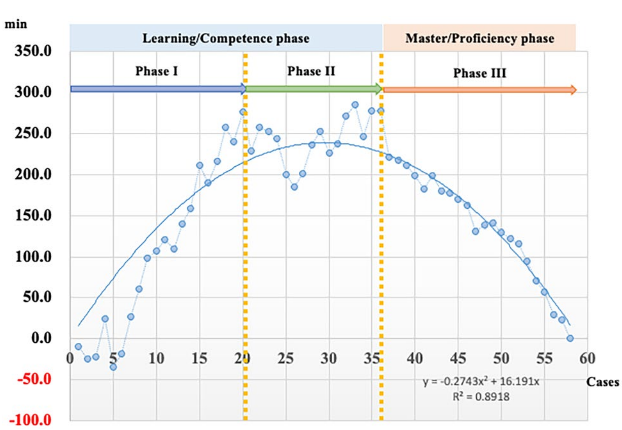

Fig. 3 Three phases of lateral lymph node dissection operative time in terms of the cumulative sum (CUSUM) learning curve

Postoperative complications in the three learning phases

Postoperative complications are shown in Table 4. No surgical mortality was seen in any group. Regarding overall complications, all-grade CD or CD grade ≥ III complications occurred most commonly in phases 1 and 2 ($P < 0.01$, $P = 0.04$, respectively). The severe complications (CD grade ≥ III) in phase 1 and 2 occurred in four patients. The severe complications (CD grade ≥ III) in phase 1 were anastomosis leakage ($n = 1$) and lateral pelvic abscess in the obturator LN area ($n = 1$), and in phase 2 were anastomosis leakage ($n = 1$) and central pelvic abscess ($n = 1$). It is probably that the lateral pelvic abscess in the obturator LN area in phase 1 was directly related to LLND. Rates of lymphocele and obturator neuropathy showed no significant differences between phases 1 and 2 compared with phase 3, although the rate of urinary dysfunction was decreased in phase 3 ($P = 0.02$). Regarding the postoperative urinary dysfunction, the proportion of patients who required medication was 6.8%, who required self-catheterization was 3.4%, and who needed reinsertion of Foley catheter after the removal was 3.4%. The median removal of Foley catheter was 4 days (range 3–7 days). No significant differences were observed between groups in terms of rates of reoperation or other postoperative complications. Regarding complications directly related to LLND, the rate of all-grade CD complications was significantly decreased in phase 3 (0.0%) compared to the first two phases (22.2%, $P < 0.01$). No significant difference was apparent in terms of CD ≥ III complications. No patients in any group required reoperation directly related to LLND.

Pathological findings in the three learning phases

Pathological outcomes are summarized in Table 5. Tumor size, histology, LVI, numbers of harvested LNs or LLNs, number of LLNMs, and pathological N or M stage showed comparable results between groups. A significant difference in pathological T stage was observed between phases 1 and 2 compared with phase 3 ($P < 0.01$).

Table 2 Comparison of baseline characteristics between phase 3 and phases 1 and 2 combined

	Learning phase	Competence phase	Learning/competence phase	Master/proficiency phase	Phase 1 and 2 vs phase 3
	Phase 1 (*n* = 20)	Phase 2 (*n* = 16)	Phase 1 and 2 (*n* = 36)	Phase 3 (*n* = 22)	*P*
Sex					0.303
Male	12 (60.0)	14 (87.5)	26 (72.2)	13 (59.1)	
Female	8 (40.0)	2 (12.5)	10 (27.8)	9 (40.9)	
Age, years	60.4 ± 8.5	65.4 ± 9.2	62.6 ± 9	59.8 ± 10.8	0.373
BMI, kg/m^2	23.1 (4.3)	24 (4.6)	23.5 (4.4)	23.2 (3.9)	0.828
History of antithrombotic therapy	1 (5)	0 (0.0)	1 (2.8)	2 (9.1)	0.300
History of prior abdominal surgery	4 (20.0)	4 (25.0)	8 (22.2)	9 (40.9)	0.132
CEA, ng/ml	10.3 ± 25.3	4 ± 4.4	7.5 ± 19.1	13.6 ± 30.7	0.211
CA19-9, U/ml	20 ± 31.2	6 ± 5.7	13.9 ± 24.3	90.9 ± 254	0.094
Distance from tumor to anal verge, cm	4 ± 1.8	5 ± 1.1	4.4 ± 1.5	4.2 ± 2.3	0.679
Neoadjuvant chemotherapy	2 (10.0)	0 (0)	2 (5.6)	3 (13.6)	0.296
Clinical T stage					0.479
T1	1 (5.0)	0 (0)	1 (2.8)	1 (4.6)	
T2	1 (5.0)	1 (6.3)	2 (5.6)	1 (4.6)	
T3	16 (80.0)	15 (93.7)	31 (86.1)	16 (72.7)	
T4	2 (10)	0 (0)	2 (5.6)	4 (18.1)	
Clinical N stage, *n* (%)					0.901
N0	9 (45.0)	7 (43.8)	16 (44.4)	9 (40.9)	
N1	4 (20.0)	7 (43.8)	11 (30.6)	8 (36.4)	
N2	7 (35.0)	2 (12.4)	9 (25)	5 (22.7)	
Clinical TNM stage, *n* (%)					0.791
II	9 (45.0)	7 (43.7)	16 (44.4)	9 (40.9)	
III	11 (55.0)	9 (65.3)	20 (55.6)	13 (59.1)	

Values are given as number (percentage) or mean ± standard deviation

BMI body mass index, *CEA* carcinoembryonic antigen, *CA19-9* carbohydrate antigen 19-9

Discussion

The present study evaluated the learning curve for prophylactic bilateral RA-LLND using CUSUM analysis. Learning-associated characteristics appear particularly important to facilitate the adaptation of the colorectal surgeon to a new technique and optimize patient outcomes, but limited data are available regarding the learning curve of RA-LLND. The current CUSUM analysis identified three phases of the learning curve for prophylactic bilateral RA-LLND for lower RC: phase 1 (learning period, cases 1–20); phase 2 (competence period, cases 21–36); and phase 3 (mastery/proficiency period, cases 37–58). RA-LLND could be performed safely during different learning phases.

Our data were comparable to those in the literature in three main ways. The first is the comparison of learning curves using the CUSUM methodology in the different phases. In the present study, the learning curve consisted of three phases. Throughout cases 1–20, CUSUM increased rapidly. After the 20th case, the learning curve entered a plateau phase. From case 37, we observed another modification of the curves, with a further trend downward. Reviewing the existing literature, three studies have reported on the learning curve for RA-LLND. The first was an analysis of the learning curve for unilateral RA-LLND using CUSUM methodology. Zhang et al. concluded that the learning curve comprised the following three phases: phase I (cases 1–51); phase II (cases 52–83); and phase III (cases 84–130) [18]. The second was a learning curve analysis for minimally invasive LLND, reported by Sukumar et al. According to the CUSUM analysis used to detect differences in performance with respect to LN yield, they suggested the minimally invasive LLND learning curve was overcome after the 19th case [20]. The third was an analysis of the learning curve for robotic TME + LLND concluded by Kawai et al. The learning curve was divided into an initial phase of skills acquisition (cases 1–21) and a second phase of experience in the technique (cases 22–41) [19]. All three of these studies reported 19–21 cases for bilateral LLND and 51 cases for unilateral LLND as boundary cases for the initial phase

Table 3 Comparison of surgical findings between phase 3 and phases 1 and 2 combined

	Learning phase	Competence phase	Learning/competence phase	Master/proficiency phase	Phase 1 and 2 vs phase 3
	Phase 1 (*n* = 20)	Phase 2 (*n* = 16)	Phase 1 and 2 (*n* = 36)	Phase 3 (*n* = 22)	*P*
Type of surgery					0.214
Low anterior resection	8 (40.0)	2 (12.5)	10 (27.8)	8 (36.4)	
Super-low anterior resection	8 (40.0)	8 (50.0)	16 (44.4)	5 (22.7)	
Intersphincteric resection	0 (0.0)	0 (0.0)	0 (0.0)	1 (4.5)	
Abdominoperineal resection	4 (20.0)	6 (37.5)	10 (27.8)	8 (36.4)	
Estimated operative time, min					
Total operative time	508.1 ± 64.5	525.3 ± 57.4	515.7 ± 61.2	494.5 ± 64.9	0.123
Bilateral LLND operative time	187 ± 28.8	173.3 ± 27.9	180.9 ± 28.9	160.5 ± 14.9	0.003
Estimated blood loss, ml	183 ± 168.0	105 ± 181.2	148.2 ± 175.9	40.5 ± 47.5	0.003
Intraoperative complication	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	–
Intraoperative blood transfusion	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	–
Conversion	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	–
Length of postsurgical stay, days	14.9 ± 10.1	14.3 ± 5.4	14.6 ± 8.2	14.5 ± 6.2	0.616

Values are given as number (percentage) or mean ± standard deviation

LLND lateral lymph node dissection

Table 4 Comparison of postoperative complications between phase 3 and phases 1 and 2 combined

	Learning phase	Competence phase	Learning/competence phase	Master/proficiency phase	Phase 1 and 2 vs phase 3
	Phase 1 ($n=20$)	Phase 2 ($n=16$)	Phase 1 and 2 ($n=36$)	Phase 3 ($n=22$)	*P*
Overall complications					
CD classification, all-grade	8 (40)	6 (37.5)	14 (38.8)	1 (4.5)	0.001
Anastomotic leakage[a] (excluding APR)	1/12 (8.3)	1/14 (7.1)	2/26 (7.7)	0/14 (0.0)	0.408
Ileus	2[b] (10.0)	0 (0.0)	2[b] (5.6)	1 (4.5)	0.865
Bleeding	0 (0.0)	0 (0.0)	0 (0.0)	0.0 (0.0)	–
Wound infection	0 (0.0)	1 (6.2)	1 (2.8)	0.0 (0.0)	0.326
Intrapelvic abscess	1[b] (5.0)	2 (12.5)	3[b] (8.3)	0.0 (0.0)	0.085
Lymphocele	2[b] (10.0)	0 (0.0)	2[b] (5.6)	0.0 (0.0)	0.162
Obturator neuropathy	0 (0)	2 (12.5)	2 (5.6)	0.0 (0.0)	0.162
Urinary dysfunction	5[b] (25.0)	0 (0.0)	5[b] (13.9)	0.0 (0.0)	0.024
Urinary tract infection	2[b] (10.0)	0 (0.0)	2[b] (5.6)	0.0 (0.0)	0.162
Severe complications (CD grade ≥ III)	2 (10.0)	2 (12.5)	4 (11.1)	0.0 (0.0)	0.045
Reoperation	1 (5.0)	0 (0.0)	1 (2.8)	0.0 (0.0)	0.326
30-day postoperative mortality	0 (0.0)	0 (0.0)	0.0 (0.0)	0.0 (0.0)	–
Complications directly related to LLND					
CD classification, all-grade	6 (30.3)	2 (12.5)	8 (22.2)	0 (0.0)	0.003
Severe complications (CD grade ≥ III)	1 (5.0)	0 (0.0)	1 (2.8)	0.0 (0.0)	0.326
Reoperation	0 (0.0)	0 (0.0)	0 (0.0)	0.0 (0.0)	–
30-day postoperative mortality	0 (0.0)	0 (0.0)	0.0 (0.0)	0.0 (0.0)	–

Values are given as number (percentage)

CD Clavien–Dindo classification, *APR* abdonimoperineal resection, *LLND* lateral lymph node dissection

[a]The analysis of anastomosis leakage was excluded abdominoperineal resection

[b]Overlapped

of the learning curve [18–20], similar to our own findings. Regarding the competence phase, we observed an abrupt modification of curves, which showed an undulating plateau. This second phase could be interpreted as the accumulation of additional experience after the initial learning curve and as the consolidation of experience gained during the first phase. Regarding the master/proficiency phase, finally, mastery could be achieved with 36 cases. From the 37th case, we observed another modification in the curve, with a further trend downward, suggesting the acquisition of higher competence in the execution of this surgical procedure. Our findings demonstrated that the mastery phase resulted in shorter LLND operative time, less blood loss, and fewer postoperative complications directly related to LLND than the learning/competence phase.

A second aspect is intra- or postoperative complication. When studying the learning curve for a new skill, the risk of intra- or postoperative complications is important. In our study, no intraoperative complications were encountered in any group. With regard to postoperative complications directly related to LLND, urinary dysfunction, obturator neuropathies, intrapelvic abscess, and lymphocele are major issues. The danger points for nerve injury are the pelvic plexus, obturator nerve, and sciatic nerve, all of which are easily injured by avulsion or direct trauma. In addition, traction or avulsion during lymph node dissection, without direct injury to the hypogastric nerve plexus or obturator nerve, is closely related to postoperative urinary dysfunction or obturator neuropathy. In the present study, fewer postoperative complications (CD all-grade) directly related to LLND occurred in phase 3 than in phases 1 and 2 combined ($P<0.01$). Reviewing the existing literature regarding postoperative complications, rates of postoperative complications for RA-LLND range from 25% to 39% [10, 26–30], compatible with the present result of approximately 26%. The rate of severe postoperative complications (CD grade ≥ III) was also consistent with previous reports [29]. Although no significant difference was seen in terms of obstructive neuropathies, intrapelvic abscess, or lymphocele, the urinary dysfunction rate was significantly lower in phase 3 than in phases 1 and 2 combined in this study

Table 5 Comparison of pathological findings between phase 3 and phases 1 and 2 combined

	Learning phase	Competence phase	Learning/competence phase	Master/proficiency phase	Phase 1 and 2 vs phase 3
	Phase 1 ($n = 20$)	Phase 2 ($n = 16$)	Phase 1 and 2 ($n = 36$)	Phase 3 ($n = 22$)	*P*
Tumor size, mm	49.6 ± 13.4	56.8 ± 14.0	52.8 ± 13.9	49.5 ± 18.7	0.543
Histology					0.207
por/sig/muc	4 (20.0)	5 (31.2)	9 (25)	9 (40.9)	
Lymphovascular invasion	19 (95.0)	13 (81.3)	32 (88.9)	18 (81.8)	0.454
Pathological T stage					0.004
T1	1 (5)	0 (0.0)	1 (2.8)	2 (9.1))	
T2	2 (10)	2 (12.5)	4 (11.1)	5 (22.7)	
T3	15 (75)	13 (81.2)	28 (77.8)	7 (31.8)	
T4	2 (10)	1 (6.3)	3 (8.3)	8 (36.4)	
Pathological N stage					0.650
N0	9 (45.0)	4 (25.0)	13 (36.1)	10 (45.5)	
N1	3 (15.0)	8 (50.0)	11 (30.6)	8 (36.4)	
N2	3 (15.0)	0 (0.0)	3 (8.3)	1 (4.5)	
N3	5 (25.0)	4 (25.0)	9 (25)	3 (13.6)	
Pathological TNM stage					0.318
I	1 (5.0)	1 (6.2)	2 (5.6)	4 (18.2)	
II	8 (40.0)	4 (25.0)	12 (33.3)	6 (27.3)	
III	11 (55)	11 (68.8)	22 (61.1)	12 (54.5)	
Number of LNs harvested					
Total LNs	37 ± 13.2	29 ± 5.8	33.7 ± 11.2	30.5 ± 7.6	0.331
LLNs	18 ± 5.8	13 ± 4.2	15.5 ± 5.5	13.7 ± 4.3	0.137
#263 LNs	4.6 ± 3.4	3.3 ± 2.7	4 ± 3.1	2.6 ± 2.6	0.060
#283 LNs	12.9 ± 4.8	9.9 ± 3.7	11.5 ± 4.5	11.3 ± 3.2	0.967
Number of LLN metastases	5 (25.0)	4 (25)	9 (25)	2 (9.1)	0.117
#263 LNs	1 (5.0)	1 (6.3)	2 (5.7)	0 (0.0)	0.162
#283 LNs	4 (20)	3 (18.7)	7 (19.4)	2 (9.1)	0.275

Values are given as number (percentage) or mean ± standard deviation

por poorly differentiated adenocarcinoma, *muc* mucinous carcinoma, *sig* signet ring cell carcinoma, *LN* lymph node, *LLN* lateral lymph node

($P=0.04$), indicating that mastery of RA-LLND may reduce the risk of postoperative urinary dysfunction.

The final aspect is the number of LLNs harvested. The pathological parameter of the number of harvested LLNs indicates the surgical quality of LLND. In our study, no significant differences in the number of harvested LNs were seen between different phases. The median number of LLNs harvested was 14, including 3 from #263LNs and 11 from #283LNs. Sugihara et al. reported the median number of LLNs harvested from patients undergoing open bilateral LLND was 17 (range 0–66). Kagawa et al. reported the median number of LLNs harvested from patients undergoing bilateral RA-LLND was 19 (range 5–47) [30]. In other reports, the median number of LLNs retrieved ranged from 4 to 10. Such findings are comparable to the median number of LLNs harvested in the present study. However, it is unclear why the number of harvested LLNs after learning decreased in this study because the dissection area (#263 and #283) did not change. Further research is required to evaluate the number of harvested LLNs before and after learning. In addition, LLNs need to be divided into different regions according to anatomic location, namely #263 for the internal iliac region and #283 for the obturator region. With regard to the results of LLN according to different regions, Zhang et al. reported the number of #263LNs harvested by RA-LLND as 3 [11], comparable with our findings. On the other hand, the number of #283LNs harvested in our study was 13.3, higher than previously reported [11].

One of the strengths of our study was the focus on learning curve for prophylactic bilateral RA-LLND. Another strength was that the present study was performed in a high-volume center in Japan with expertise in lateral pelvic anatomy and LLND. Nevertheless, our study has several limitations. First, this was a retrospective study, Second, all surgical procedures in this study were performed by multiple surgeons at a single institution. Although the learning curve is usually surgeon dependent, it is reported that robotic-assisted surgery also relies on other variables inherent to the institution, such as the institution's program [31]. Actually, the establishment of a robotic-assisted LLND surgery program requires a high volume of cases. The data in this study are our institutional overall experiences. Hence the data are institutional learning curve, and must be applied with caution. In addition, an ideal study would include many surgeons with different levels of experience from several institutions. Third, the influence of neoadjuvant therapy for LLND remains unclear because of the lack of neoadjuvant therapy in the majority of cases in this study. In addition, we did not include therapeutic LLND cases in our analysis. The reason is that therapeutic LLND requires more complex procedures such as combined resection of blood vessels or nerves than prophylactic LLND. We consider therapeutic LLND to be the next step after prophylactic LLND. Thus, our analysis may be limited in the rest of the world because of lack of neoadjuvant therapy in the majority of cases, bilateral LLND in a single case, or prophylactic LLND without therapeutic LLND. Further investigation and evaluation of learning curves for these cases would therefore be needed. Fourth, Japanese surgeons are much more experienced in prophylactic bilateral LLND compared with Western surgeons, and a learning curve would be different from those who learn prophylactic bilateral RA-LLND without prior exposure to the prophylactic bilateral LLND. These are potential biases that may have affected the learning curve. Therefore, the data need to be interpreted with caution and may not necessarily be applicable to the rest of the world. Fifth, during this study period, the non-robotic certified surgeons performed prophylactic bilateral laparoscopic LLND in our institution; such patients have not been included in this analysis. Finally, there is no data on the learning curve of laparoscopic LLND in our analysis. The difference in the comparison with laparoscopic LLND is therefore unknown.

Conclusion

The current CUSUM analysis revealed characteristics of the learning curve for prophylactic bilateral RA-LLND. These findings suggest that the initial stage of the learning curve comprises 20 cases, with mastery achieved from the 36th case.

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Data availability The datasets used and analyzed during the current study are available from the corresponding author on reasonable request.

Declarations

Conflict of interest The authors declare no competing interests.

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