



Original Article

Learning curve in concurrent application of laparoscopic and robotic-assisted hysterectomy with lymphadenectomy in endometrial cancer

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ABSTRACT

Objective: To evaluate the concurrent interaction of laparoscopic and robotic-assisted surgery in the initial learning period of endometrial cancer staging.**Materials and methods:** A retrospective cohort study was performed for the first 44 consecutive patients with endometrial cancer underwent laparoscopic (LSS) or robotic-assisted staging surgery (RSS) from February 2012 to October 2015 by a single surgeon in a tertiary care referral hospital. Demographics, diagnosis, perioperative variables, and complications were recorded. Quality of surgery was determined by the number of lymph nodes dissected and learning curve was estimated by operative time with respect to chronologic order of operation.**Results:** Twenty-four patients received LSS and 20 patients received RSS. RSS required longer operative time, but obtained more total number of lymph nodes compared with LSS (286.9 vs. 201.9 min ($p < 0.001$); 26.2 vs. 20.7 ($p < 0.05$), respectively. There were no difference in blood loss, number of para-aortic nodes removed, complications and hospital stay between the two types of surgery. An additive model based on tumor grade, body mass index, estimated blood loss and chronological order of operation was constructed to fit operative time of these two types of surgery. Proficiency of achievement was not observed for LSS and was 6 for RSS.**Conclusions:** Operative time was longer but Lymph node dissection was easier in RSS. Learning curve for LSS to maintain similar surgical quality as RSS was not observed. The concurrent use of robotic platform in the initial practice of minimally invasive staging surgery could optimize surgical technique for LSS.© 2017 Taiwan Association of Obstetrics & Gynecology. Publishing services by Elsevier B.V. This is an open access article under the CC BY-NC-ND license (<http://creativecommons.org/licenses/by-nc-nd/4.0/>).

Introduction

The incidence of endometrial cancer is rapidly increasing worldwide with the highest disease burden reported in North America and Western Europe. In Taiwan, around 1500 to 2000 new cases of

endometrial cancer were diagnosed annually, and the number of cases rose rapidly (Supplementary Figure). In 2013, endometrial cancer was the 12th leading cause of death in Taiwanese women (<http://www.hpa.gov.tw/BHPNet/Web/Stat/Statistics.aspx>). Surgical staging is the mainstay of initial therapy for endometrial cancer. According to 2009 Federation of Gynecology and Obstetrics (FIGO) cancer staging system, the standard staging surgeries for endometrial cancer are hysterectomy, adnexectomy, and pelvic lymph node dissection (PLND) and para-aortic lymph node dissection (PALND). Such surgeries are traditionally approached by exploratory laparotomy through a midline incision. Minimally invasive surgery through laparoscopy is an alternative surgical approach that is associated with fewer complications, shorter hospitalization, faster recuperation [1], similar cancer recurrent rates and patient survival outcome compare

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with laparotomy [2,3], even when endometrial cancer at high grade [4]. In the ESMO-ESGO-ESTRO Consensus Conference meeting [5], minimally invasive surgery was recommended for surgical management of endometrial cancer.

Da Vinci Surgical System (Intuitive Surgical, Inc.) platform was introduced and approved by the US Food and Drug Administration (FDA) since 2005 for gynecologic surgical procedures. Applications included but not limited to hysterectomy, adnexal surgery, myomectomy, tubal reanastomosis, sacrocolpopexy, and staging and management of gynecologic malignancies. Robotic-assisted laparoscopic surgery was found superior than laparoscopy due to its advanced technology from enhanced visualization, wristed instrumentation, and improved ergonomics such that, more complex cases and more difficult procedures could be performed by surgeons who had less laparoscopic experience. Patients benefited from robotic surgeries by having less blood loss, less postoperative pain, and shorter hospital stay than laparoscopy [6,7]. Taiwan adopted the robotic system rapidly and so far, we had installed more than 30 robotic systems since year 2004. In the USA, robotic-assisted staging surgeries (RSS) were increasing among gynecologic oncologists since the emergence of robotic platform [8]. Taiwanese population also has accepted robotic as their possible choice of surgery [9]. However, debates of using robotic surgeries instead of laparoscopic surgeries have been raised since the costliness of robotic system [6]. Socioeconomic status and hospital characteristics were also factors that limited the application of robotic surgeries [10]. Therefore, competence in handling laparoscopic staging surgery (LSS) is still necessary to many surgeons. Many operators preferred RSS than LSS due to the shorter learning curve for robotic surgery [6]. Such reports were based on comparative studies using historic controls, when the operators were experts in LSS before their first approach to RSS [6]. Nowadays, many beginners are trained to perform staging surgery when both robotic and laparoscopic facilities are available. We started our LSS and RSS in such condition.

In this study, we analyzed the learning curves of LSS and RSS when both were available at the same time. We studied the interaction of these two types of surgeries in the initial practice of minimally invasive staging surgery in endometrial cancer. We aim to seek for the possible benefits of this situation in the practice of LSS

Materials and methods

Patients

A retrospective study was conducted that included the first 44 consecutive cases of LSS or RSS for the indication of endometrial cancer by a local board certified gynecology oncologic surgeon (PLT), who had several years of experience in laparoscopic surgeries in benign gynecological diseases. Dates of accrual for patients were from February 2012 to October 2015 from a single institute. Approval was received from the institutional review board of National Taiwan University Hospital, Taiwan (201510088RINA).

Surgical techniques

Abdominal hysterectomy with PLND was a routine surgical procedure in patients with endometrial cancer in our study institute. Very few patients received laparoscopic staging surgeries before this study and PALND was not a routine surgical procedure. PALND was first established in this study, then was routinely performed unless difficulty in approaching. Standard anatomic landmarks were used for PLND and PALND. PLND was performed to the pelvic level and PALND was performed from the mid-common iliac vessels cephalad to approximately the level of the inferior mesenteric artery.

Robotic surgery using Da Vinci surgical system (Intuitive Surgical, Sunnyvale, CA) was available in our institute since January, 2012. To credential the requirements for gynecologic robotic surgery, the surgeon received an 8-h animal surgical laboratory, completed a 4 h robotic surgical time utilizing simulator and observed 2 gynecologic robotic procedures at other institutes. The first RSS was performed on March, 2012, as the 2nd consecutive case of this study. Robotic surgery was not covered by national health insurance system of Taiwan, so patients had to self-pay about ten times higher cost than laparoscopic surgery in our society (<http://nhi.gov.tw/>). Therefore, randomized study was not applicable and our patients with clinical localized endometrial cancer were treated by LSS in general. Only patients who could afford the cost for robotic surgery were included for RSS.

Standard technique for the LSS included uterine manipulator (Valtchev uterine mobilizer) placement; initial peritoneal insufflation using Veress needle; placement of a 5-mm umbilical port or a 12-mm supra-umbilical port for zero or 30° camera, placement of 2 additional 5-mm ports and 1 additional 12-mm ports at the right and left lower abdomen. Uterine specimens were removed vaginally with vaginal morcellation in bag as necessary. Vaginal stump closure was performed via vaginal approach.

In RSS, a 12-mm supra-umbilical port was inserted for zero degree or 30° camera. Three additional 8-mm ports for the robotic instruments and one 12-mm assistant port were placed at bilateral sides of abdomen. Uterine specimens were removed vaginally. Cases with huge uterus containing large leiomyomas were placed in endobags before vaginal morcellation. Vaginal stump closure was performed using robotic arms.

Outcome measurements

The following parameters were recorded: age at time of surgery, body mass index (BMI, calculated as weight in kilograms divided by the square of height in meters), total operative time (defined as first skin incision to skin closure), estimated blood loss, histological subtypes, tumor grades, FIGO staging, number and location of lymph nodes dissected, and post-surgical length of hospital stay. Immediate intraoperative and postoperative complications such as bowel, bladder, ureteral, and vascular injuries; transfusions; postoperative fever, ileus, vaginal cuff dehiscence, and conversions were also tracked.

Statistical analysis

Pearson's correlation coefficient was used to estimate the correlations between operation time and perioperative outcomes. Multiple linear regression analysis was used to evaluate the determinants of operation time. Two smooth functions were added to the regression equation for comparing operative time of LSS with RSS during early learning phase of endometrial cancer staging.

Statistical analysis was performed using Statistical Analysis System (SAS) version 8.0 (SAS Institute, Cary, NC) and R (<https://www.R-project.org>). Continuous variables reported as mean and standard deviation, while discrete variables were reported as percentages of the total. All comparisons of continuous variables across cohorts were analyzed using a *t*-test and discrete variables were compared between groups using a chi-squared test. In the case of small cells, Fisher's exact test was used. In all instances, a two-tailed *p*-value of < 0.05 was considered statistically significant.

Results

Distribution of LSS and RSS across the study

Twenty-four patients underwent LSS and 20 patients underwent RSS for clinical localized endometrial cancer. The first RSS was

performed as the 2nd case of the study. In total, 45.5% of the patients received RSS. Distribution of LSS and RSS across the study years is shown in Fig. 1. The number of RSS for endometrial cancer increased with the chronological order.

Comparison of basic clinical data

The mean age of the patients was 56.9 ± 7.1 , range from 43 to 72 years. There was no difference in age and body mass index between the two groups. The demographic data of FIGO staging, tumor grades and histology subtypes were shown in Table 1. Majority of patients were diagnosed as FIGO stage 1A and 1B, and 90.9% of patients were grade 1. Forty-one cases were diagnosed as endometrioid adenocarcinoma and 3 cases were carcinosarcoma: 1 patient received LSS and 2 patients received RSS.

Assessment of surgical outcome

The perioperative outcome and complications are shown in Table 2. The mean operative time for RSS exceeded the LSS by 85 (286.9 ± 76.7 , range 200–471, versus 201.9 ± 50.2 , range 102–318, $p < 0.001$) min. Though not statistically significant, EBL was 111 ml less for LSS compared with RSS (122.5 ± 110.2 , range 20–450 mL versus 233.5 ± 430.2 , range 20–2000 mL). In LSS, one patient was complicated with obturator nerve injury and received rehabilitation after surgery. One patient diagnosed with carcinosarcoma had large uterine size (18 cm \times 15 cm \times 15 cm) and was converted to laparotomy via pfannenstiel skin incision. In the RSS, one patient with BMI of 46.7 had excessive blood loss (2000 mL) that required blood transfusion. One patient diagnosed as carcinosarcoma was found to have tumor invasion into bladder during surgery. Her bladder was perforated during tumor excision and was primarily repaired by robotic assistant surgery. One patient was complicated with vaginal cuff dehiscence diagnosed 10 days after operation and received primary cuff repair through vagina approach. Her vaginal cuff was closed by continuous 0-Vicryl (Ethicon Inc.) suture during RSS. Overall, there were no differences in blood loss, complications and hospital stay between the two types of surgery.

Assessment of lymph nodes retrieval

Lymph node counts were evaluated to validate quality of surgery. PLND and total (PLND and PALND) number dissected was significantly higher using RSS compared with LSS ($p < 0.05$). There was no difference in the PALND number in the two groups. Numbers of lymph nodes dissected with chronological order of operation were rather consistent in both groups (Fig. 2).

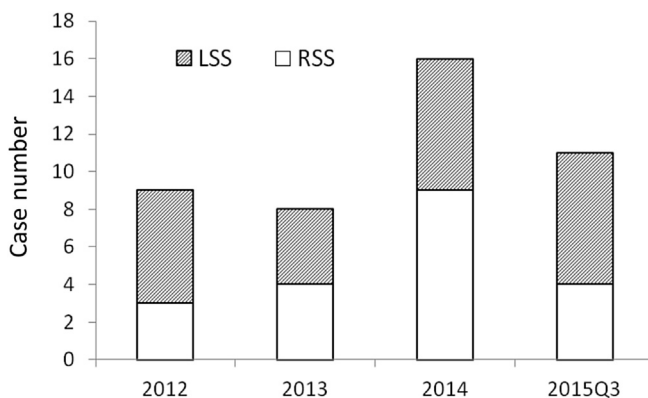


Fig. 1. The yearly growth of LSS and RSS in endometrial cancer. Q: quarter of year.

Evaluation of operative time

Pearson correlation test was used to examine associations between operative time and operative outcomes, included BMI, blood loss, surgical type, number of PLND and PALND, tumor grade by type of surgery and total number of lymph nodes by type of surgery. We found a significant increase in operative time with larger amount of blood loss ($p < 0.001$). Operative time was not influenced by the number of lymph nodes dissected, either through LSS or RSS. However, operative time for RSS in treating grade 3 endometrial cancer was 73 min longer comparing with grade 1 patients with either type of surgery ($p = 0.04$) (Table 3).

Model of learning curve

To study learning curves in these two types of surgery, we proposed a generalized additive model to fit the outcome data of these 44 consecutive patients. The response variable was operative time and the covariates considered for adjusting the effects on operative time in the model were based on the results from Pearson correlation test. The experience effects of each surgical type on operative time were modeled with a cubic spline smooth function and denoted as $s(\text{experience})$ in the formula of the model:

$$\text{Operative Time} = \text{BMI} + \text{Log EBL} + \text{Type} + \text{Total} + \text{grade} \\ : \text{Type} + \text{Total} : \text{Type} + s(\text{experience}) : \text{Type}$$

where BMI, EBL, Type, grade, and Total represents body mass index, estimated blood loss, type of surgery (either LSS or RSS), tumor grade, and total number of lymph nodes retrieved, respectively.

The estimated mean subtracted learning curves for the two types of surgeries are given in Fig. 3. The curve for LSS was flat over the 24 operations, suggested no significant gains in operation time from experience over the 24 operations. The curve for RSS showed a large wave at the first 6 operations, and swigged within a 95% confidence band covering 0 to the end of 20 operations.

Discussion

We demonstrated our initial experience in concurrent application of LSS and RSS in patients with endometrial cancer. An 85 min longer operative time but earlier decrease in operative time across study period could be observed in RSS compared with LSS. To explore such difference, we first analyzed surgical quality by calculating the number of lymph nodes dissected along with the surgical chronological order. RSS yielded more total and pelvic lymph nodes, but not para-aortic lymph nodes which are technically more difficult, than LSS. However, both types of surgeries showed stable lymph nodes counts with operative chronological order. We then included all peri-operative factors that could influence operative time and formulated an additive model to estimate learning curves for these two types of surgeries. Learning time to establish optimum surgical quality was not obvious for LSS compared with RSS.

PLND and PALND are necessary for FIGO cancer staging system in endometrial cancer, aiming as a guideline for further treatment and as an indicator to predict survival outcome. Although a meta-analysis of two randomized trials on the impact of systematic lymphadenectomy in early-stage endometrial cancer showed no benefit on overall and recurrence-free survival [11,12], extensive PLND as well as PALND was demonstrated to have survival benefit in patients with intermediate- or high-risk endometrial cancer [13–16]. Therefore, the number of lymph node dissected had been commonly used for assessing the thoroughness of

Table 1

Clinical and pathologic characteristics of patients undergoing LSS and RSS for endometrial cancer.

	LSS (N = 24)	RSS (N = 20)	p value
Age, mean \pm SD (range) year	57.0 \pm 5.5 (44–65)	56.4 \pm 7.7 (43–72)	0.77 ^a
Body mass index, mean \pm SD (range) kg/m ²	24.6 \pm 5.1 (16.7–37.3)	26.1 \pm 7.3 (19.1–46.7)	0.43 ^a
FIGO stage, N (%)			
Ia	16 (66.7)	12 (60.0)	
Ib	5 (20.8)	2 (10.0)	
II	0	0	
IIIA	0	2 (10.0)	
IIIB	1 (4.2)	2 (10.0)	
IIIC1	0	0	
IIIC2	2 (8.3)	0	
IVA	0	1 (5.0)	
IVB	0	1 (5.0)	
Histology, N (%)			0.58 ^c
Endometrioid	23 (95.8)	18 (90.0)	
Carcinosarcoma	1 (4.2)	2 (10.0)	
Grade, N (%)			0.43 ^b
1	20 (83.3)	14 (70.0)	
2	3 (12.5)	3 (15.0)	
3	1 (4.2)	3 (15.0)	

^a t-test.^b Chi-square test.^c Fisher's exact test.**Table 2**

Comparison of perioperative outcomes between LSS and RSS in patients with endometrial cancer.

	LSS (N = 24)	RSS (N = 20)	p value
Operative time, mean \pm SD (range) min	201.9 \pm 50.2 (102–318)	286.9 \pm 76.7 (200–471)	<0.001 ^a
Blood loss, mean \pm SD (range) mL	122.5 \pm 110.2 (20–450)	233.5 \pm 430.2 (20–2000)	0.23 ^a
Lymph nodes count, mean \pm SD (range)			
Para-aortic	6.0 \pm 3.9 (0–17)	6.2 \pm 5.4 (0–19)	0.89 ^a
Pelvic	14.7 \pm 5.5 (5–27)	19.6 \pm 7.3 (1–33)	0.015 ^a
Total	20.7 \pm 6.6 (8–33)	26.2 \pm 11.0 (1–49)	0.047 ^a
Complication, N (%)	2 (8.3)	3 (15.0)	0.65 ^b
Conversion	1(4.2)		
Damage to obturator nerve	1(4.2)		
Blood transfusion		1 (5)	
Bladder perforation		1 (5)	
Vaginal cuff dehiscence		1 (5)	
Hospital stay, mean \pm SD (range) days	3.8 \pm 1.3 (3–8)	3.9 \pm 1.6 (3–10)	0.82 ^a

^a t-test.^b Fisher's exact test.

lymphadenectomy [16]. Laparoscopic PLND and PALND in endometrial cancer were first described in 1992 [17]. But such procedures were not well accepted and were not performed in early randomized trials that compared laparotomy with laparoscopic surgery in early-stage endometrial cancer [18]. In later randomized trials, only PLND, but not PALND was performed [19]. In more recent LAP2 study, a largest randomized trial in LSS in endometrial cancer that included 1682 patients, lymphadenectomy was performed in the majority of cases. In this study, PALND was completed in 94% of patients and PLND was performed in 98% of patients. However, the conversion rate was high. 25.8% of patients assigned to the LSS group were converted to laparotomy [20]. A statement of 'poor visibility' was reported in 14.6% of cases in the LSS group. These results reflected the difficulty of laparoscopic lymphadenectomy. Kohler et al. stated that a learning period of approximately 20 procedures was required to maintain a constant number of PLND yield, while PALND up to left infrarenal area took longer learning time in LSS [21]. With more advancement in surgical equipment and wide sharing of surgical experiences, conversion rates in minimal invasive staging surgeries became lower, especially when RSS was included [6,22]. A large cohort study included 503 patients with RSS showed that the success rate of lymphadenectomy was as high as 92.6%, (when more than 68% of patients

received PALND), with only 6.4% conversion rate and short-term complications [23]. Modification of robotic docking technique could give an even higher success rate of PALND based on aortic lymph node count [24].

The advanced technology of robotic-assisted laparoscopy gives advantages for performing these difficult surgical procedures. Many studies had reported their initial experience with robotic surgery and showed the feasibility of RSS in endometrial cancer [25–30]. Proficiency, which was defined as the point at which the slope of the learning curve became less steep for operative times, was reported higher for LSS than for RSS [6]. Proficiency for PLND and PALND was achieved at 49th cases in LSS [29], but at 20 to 24 cases in RSS [28,29]. It was found that proficiency could be even faster (less than 10) when operation was performed by surgical partners with similar competence [30]. These studies reporting on learning curve and proficiency of early experience of RSS in endometrial cancer were based on historical comparison of previous experiences with LSS. These surgeons were well experienced with LSS when they first approached the RSS. Currently, surgeons were trained to perform staging surgery in endometrial cancer when laparoscopic device was available with robotic platform.

We reported our initial experience in minimally invasive staging surgery when both types of surgical devices were concurrently

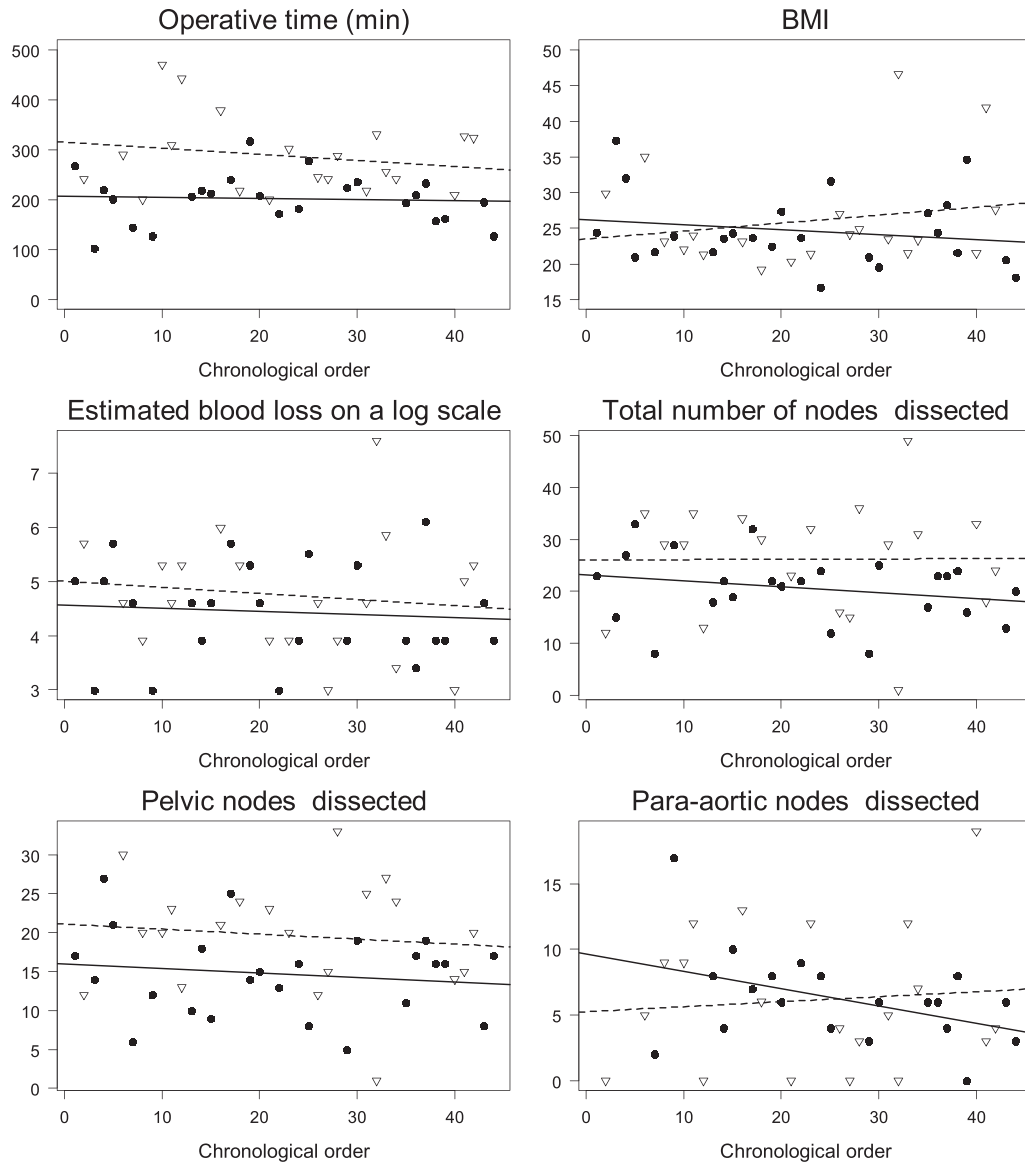


Fig. 2. Operative time, BMI, EBL (log scale was used due to a case with extreme high out-layer) and numbers of lymph nodes (total, pelvic and para-aortic) dissected according to chronological order of LSS and RSS in endometrial cancer. Solid circles and lines represent as LSS. Blank triangles and dash lines represent as RSS.

Table 3

Variables in correlation with operative time.

Parameters, mean \pm SD	Operative time	
	Coefficient	p value
Intercept	39.23 \pm 57.12	0.50
BMI	-1.18 \pm 1.45	0.42
Log EBL	41.62 \pm 8.58	<0.0001
RSS	93.47 \pm 46.16	0.05
Total number of node dissected	0.79 \pm 1.64	0.63
LSS		
Grade 1	1	
Grade 2	-63.33 \pm 30.99	0.05
Grade 3	-32.99 \pm 51.96	0.53
RSS		
Grade 1	1	
Grade 2	-8.21 \pm 39.99	0.84
Grade 3	72.99 \pm 34.01	0.04
Total number of node dissected		
LSS	1	
RSS	-1.58 \pm 1.95	0.42

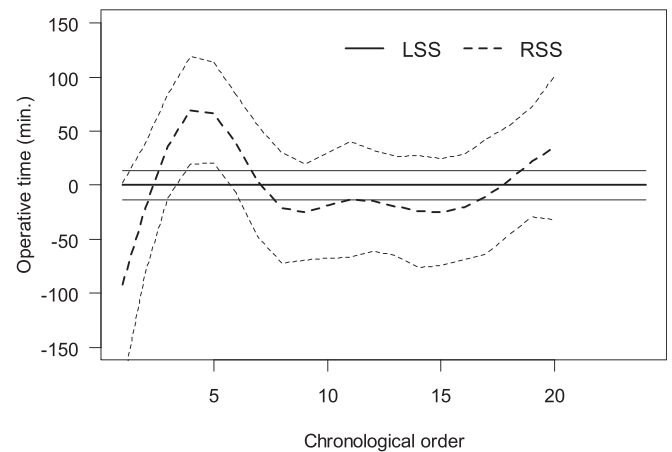


Fig. 3. The estimated learning curves with means subtracted for LSS (solid lines) and RSS (dash lines) in endometrial cancer.

performed by an experienced laparoscopic surgeon who had very few experience in laparotomic PALND. During our initial application of these two types of surgery, we found operative time 85 min longer for RSS compared with LSS. When proficiencies of these two types of staging surgery were further analyzed with lymphadenectomy count as validation of surgical quality, learning time for LSS was not observed and proficiency of achievement was 6 for RSS. These numbers were much lower than reported [6,21,28–30]. This suggested a possible cross-over self-learning benefits of these two types of surgery when both were performed concurrently. The surgeon could have obtained skill of lymphadenectomy using RSS to master LSS.

Extensive lymphadenectomy during staging surgery could increase un-necessary complications, such as excessive bleeding, infection, lymph edema, and lymphocyst formation. Currently, sentinel lymph node mapping was reported to be a resolution to minimize lymph node dissection without compromising staging accuracy. Sentinel lymph node mapping was found to have high accuracy in detecting lymph node metastasis and may improve survival outcome in patients with early endometrial cancer [31]. Dissecting sentinel lymph nodes instead of extensive lymph node dissection could be very promising for minimal invasive surgery beginners. Learning time could then be even shorter in staging surgery in endometrial cancer.

Small patient cohort is a major limitation of this study. We have included more cases in later years of study, yet the amount is still low. More frequent surgical practice could have resulted with even shorter learning time for surgery. In addition, operative time could be affected profoundly when dealing with low-volume operations containing patients with variety of clinical characteristics at the beginning of using new surgical instruments for new surgical procedures. In our study, a patient who was diagnosed as carcinosarcoma during RSS was found to have bladder invasion that required robotic-assisted bladder repair. Another patient with carcinosarcoma during LSS was found to have huge uterine size and was converted to laparotomy. Operative time was therefore very much different between these two cases. Using Pearson correlation test, we were able to identify confounding factors that could have influenced operative time. We found a 73 min longer operative time in grade 3 endometrial cancer compared with grade 1 endometrial cancer with either type of surgery. All other confounding factors found from Pearson's correlation test were included in the additive model to calculate learning curves of surgery.

Obesity is another clinical characteristic that is technically challenging. It is associated with potentially higher operative complications that could affect operative time during staging surgery. Staging surgeries in obese ($\text{BMI} \geq 30 \text{ kg/m}^2$) women was claimed to have lower postoperative complications using minimal invasive approaches compared with open surgery [32]. Morbidly obese ($\text{BMI} \geq 40 \text{ kg/m}^2$) women were found to have similar less complication in laparoscopic approach and robotic surgeries [33]. We had 9 obese and 2 morbidly obese patients. The two morbidly obese patients were intentionally assigned to RSS. Longer operative time (327 and 331 min) was required in both patients, and one of them with BMI 46.7 had only 1 PLND and was complicated with massive bleeding during operation that required blood transfusion. Morbidly obese is uncommon in our society and required more surgical experience even to an experienced laparoscopist.

One of our patients who received RSS was complicated with vaginal cuff dehiscence. Vaginal cuff dehiscence was reported to be more common in RSS compared with LSS [34]. Early resumption of sexual activity and surgical technique were reasons related to this complication [35]. The early occurrence of vaginal cuff dehiscence in our patient could be technical related. Such complication should not be ignored in the early learning phase of robotic surgery.

Conclusions

To our knowledge, this is the first study comparing the learning curve of concurrent application of LSS with RSS by an experienced laparoscopist. Our result demonstrated that operative time was longer in RSS compared with LSS. However, technical skill was more easily obtained from RSS than LSS. Such skill obtained from robotic surgery could guide the surgeon to establish a better success in LSS.

Conflicts of interest

The authors have no conflicts of interest relevant to this article.

Appendix A. Supplementary data

Supplementary data related to this article can be found at <https://doi.org/10.1016/j.tjog.2017.10.014>.

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