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Learning curve of robotic lobectomy for lung malignancies by certified thoracic surgeons

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ABSTRACT

Video-assisted thoracic surgery (VATS) has become widespread in the last 20 years, followed by robot-assisted thoracic surgery (RATS). Few studies compared the learning curve between RATS lobectomy and conventional VATS. This study included 79 RATS lobectomy cases performed in our hospital from November 2015 to October 2019. To estimate the required number for learning, the cumulative sum method, which is to plot a value obtained by sequentially accumulating a difference from a mean value was applied. As a result, the median total operative time and the median console time for all cases were 167 minutes and 138 minutes, respectively. Firstly, for our team, 28 cases were estimated to be required for learning curve for RATS lobectomy. For individual, each surgeon might be learned in only 5 to 6 cases. By contrast, the number of cases for learning VATS lobectomy which was underwent by a 'single' surgeon from 2009 was estimated to be 35 cases. The time to dock from start operation (median 14 minutes) reached plateau in 18 cases, but the time after rollout was median of 18 minutes and there was no significant change from the beginning. In conclusion, RATS lobectomy might be a technique that could be learned in a small number of cases compared to VATS. The results of this study might be helpful for certified surgeons who tried to get started with RATS and for establishing a learning program.

Keywords: robotic lobectomy, VATS, learning curve, CUSUM

Abbreviations:
CUSUM: cumulative sum
RATS: robot-assisted thoracic surgery
VATS: video-assisted thoracic surgery

INTRODUCTION

Advances in lung cancer screening using computed tomography have led to the detection of many early lung cancers and, consequently, increase less invasive thoracic surgery. In fact, according to the registration data in Japan, approximately 70% of all surgeries for lung cancer

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were performed with video-assisted thoracic surgery (VATS) in 2016.[1] In other words, many Japanese surgeons are now familiar with VATS.

The current approach of thoracic surgery is diversifying with the advancement of technology, from conventional thoracotomy to VATS to robot-assisted thoracic surgery (RATS). RATS, the latest technology, has been clinically applied since around 2000, and it has been reported that RATS was useful for pulmonary resection for lung malignancy.[2-5] In Japan, RATS for lobectomy has been approved to be enforced under national healthcare insurance in 2018, it has begun to spread rapidly thereafter. However, surgeons who are skilled in VATS may be hesitant to learn RATS because of the lack of tactile sensation and the enormous cost of setup and maintenance.

Although RATS is becoming more widespread around the world, there have been few reports on its learning curve compared with VATS.[6-10] In this study, we retrospectively examine the data of RATS and VATS performed by certified thoracic surgeons in Japan, and estimate the number of cases required for learning using the cumulative sum method (CUSUM). The aim of this study was to evaluate whether RATS was superior in learning curve.

MATERIALS AND METHODS

Patients

This study was approved by the institutional review board of Nagoya University Hospital and individual patient consent was waived. From November 2015 to October 2019, 79 consecutive patients with non-small cell lung cancers (NSCLC) or metastatic lung tumors underwent lobectomy via RATS. In NSCLCs, RATS lobectomy was performed for patients with stage IA or IB in principle, which was discussed in the weekly surgical meeting. As a control group, 224 VATS lobectomies performed in our hospital from 2009 were applied and compared with the RATS group. For this retrospective study, data obtained from patient medical records included age, sex, tumor histology, tumor location, tumor size, clinical stage, surgical procedure performed and other perisurgical parameters. The 8th edition of the TNM classification for NSCLC was used for patient stratification.

Surgical procedure

We started RATS for mediastinal tumors in 2013 and started lobectomy for lung malignancies in November 2014. Initially, 15 cases were performed using the da Vinci S system, and from the 16th case the Da Vinci Xi system was updated to the present (Intuitive Surgical, Sunnyvale, CA). There were a total of five surgeons entering the console, with three performing until the 71st patient.

The patient was placed in a lateral decubitus position that allowed the hips to extend. Up to the 15th patient, under the da Vinci S system, surgery was performed from 3 ports and 2 ports for assistants, but after the introduction of da Vinci Xi system, it was changed to 4-arm technique and 1 port for assistants. The port position has changed due to the learning and experience, from April 2018, insert 3 to 4 ports from the 8th and 9th intercostal space, and the assistant operates via the foremost port. In all cases, surgery was performed under carbon dioxide insufflation of 6 mmHg. Systematic mediastinal lymph node dissection was performed in 70 cases except for metastatic lung tumor and stage 0 lung cancer.

Statistical analyses

To estimate the required number of cases for learning, the CUSUM method was adopted to this study. CUSUM is to plot a value obtained by sequentially accumulating a difference from

a mean value, and the required number can be estimated from an obtained curve. The CUSUM was defined as a following formula:
CUSUM = $\sum_{i=1}^{N}(ti-tm)$, whereas ti indicates each time, and t_m indicates the mean time of all cases. The phase in which the obtained curve rises is the initial phase, and the flat part after it peaks is the consolidation phase (phase II). Phase III is until the curve goes down to zero. The boundary between phases I and II is estimated as the number required for learning.

Comparing the parameters, categorical data were compared using the chi-square test or Fisher's exact test. The Kruskal–Wallis test was used to compare differences in continuous parametric variables. P values of < 0.05 were regarded as statistically significant. Statistical calculations were performed using a statistical software package (JMP 10 and StatView 5.0; SAS Institute Inc., Cary, NC, USA).

RESULTS

Patient characteristics

Detailed patient characteristics were shown in Table 1. The median age of the cohort in this study was 70 years, with male accounting for about 40%. All the patients except for 2 patients were primary lung cancer. The histological diagnoses were all adenocarcinoma except for a carcinoid. All the patient with clinical stage I except for one stage IIA was enrolled. Right upper lobectomy was enforced the most. The median operative time was 167 minutes. The time of RATS was slightly longer because the median of 224 VATS was 150 minutes. No patients required conversion to open thoracotomy. The median length of postoperative hospital stay was 5 days. Three patients underwent pleurodesis for chylothorax and prolonged air leakage, but there were no mortality within 30 days. Thus, RATS was safe and feasible treatment as a standard of care. The surgeon performing the most operations did 37 lobectomies, and the second performed 21 cases. As a result, the top three surgeons performed 76 patients out of 79 (96%). The cases in which each of the five surgeons performed the first RATS lobectomy are shown alphabetically in Figure 1A.

Experiences of robotic surgery in each surgeon

In our institute, all operators are required to complete at least 20 hours of practice using the actual da Vinci machine and to pass our own practical test before obtaining a license. The test consisted of five items: "Forceps, Clutch, Camera Operation and Cooperative Manipulation", "Dissection", "Cutting", "Suturing", and "Protective Dissection Manipulation", and was supervised by a experienced surgeon in the hospital to determine if the test was passed or failed. Table 2 shows the five surgeons' experience in robotic surgery before their first lobectomy. All surgeons have experienced at least seven cases of operators or assistants for mediastinal tumor surgery or assistants in lobectomy using da Vinci system.

Learning curve of RATS lobectomy

The CUSUM plots for total operative time and console time were shown in Fig. 1A and 1B. According to the results, it was estimated that the number of operations required for learning was 28. Then, each learning curve of two surgeons (A, B) who started RATS during the initial cases revealed that there was a possibility that they could be learned in 5 to 6 cases (Fig. 2A and 2B). Since the Da Vinci system was changed from S to Xi, CUSUM dropped on the way in Fig. 2A, consequently showed the same rise again. The time to dock the Da Vinci was a median of 14 minutes. This was learned in 18 cases (Fig. 3A), while the time after roll-out was a median of 18 minutes with no significant change from the beginning (Fig. 3B). Table 3 shows the results of stratifying patients into Phases I, II, and III and comparing each factor. The time related to the operation was shortened in the order of I, II, and III, while the other factors were not significantly different among the three groups.

Table 1 Overall patient characteristics and perioperative outcomes (N = 79)

Patient characteristics		
Age		70 (43–81)
Sex (%)	Female	48 (61)
	Male	31 (39)
Histology (%)	AD	76 (96)
	Other	3 (4)
Tumor size, cm		1.5±0.9
c-stage (%)	0	7 (9)
	IA	66 (84)
	IB	3 (4)
	IIA	1 (1)
Tumor location (%)	Right upper	33 (42)
	Right middle	8 (10)
	Right lower	11 (14)
	Left upper	13 (16)
	Left lower	14 (18)
Comorbidities	Diabetes	5
	Brain infarction	2
	Hepatic cirrhosis	1
	OMI	1
Intraoperative parameters		
Operative time, minutes		167 (103–376)
Blood loss, mL		10 (0–618)
Conversion to thoracotomy		0 (0)
Postoperative outcomes		
30-day morbidity (%)	Clavien I–II	4 (5)
	Clavien III–IV	4 (5)
30-day mortality (%)		0 (0)
30-day readmission (%)		0 (0)
Duration of drainage, days		2 (2–11)
Length of stay, days		5 (3–13)

Continuous data are expressed as mean ± SD or median (range).
c-stage was limited to lung cancer.
AD: adenocarcinoma
OMI: old myocardial infarction
SQ: squamous cell carcinoma.

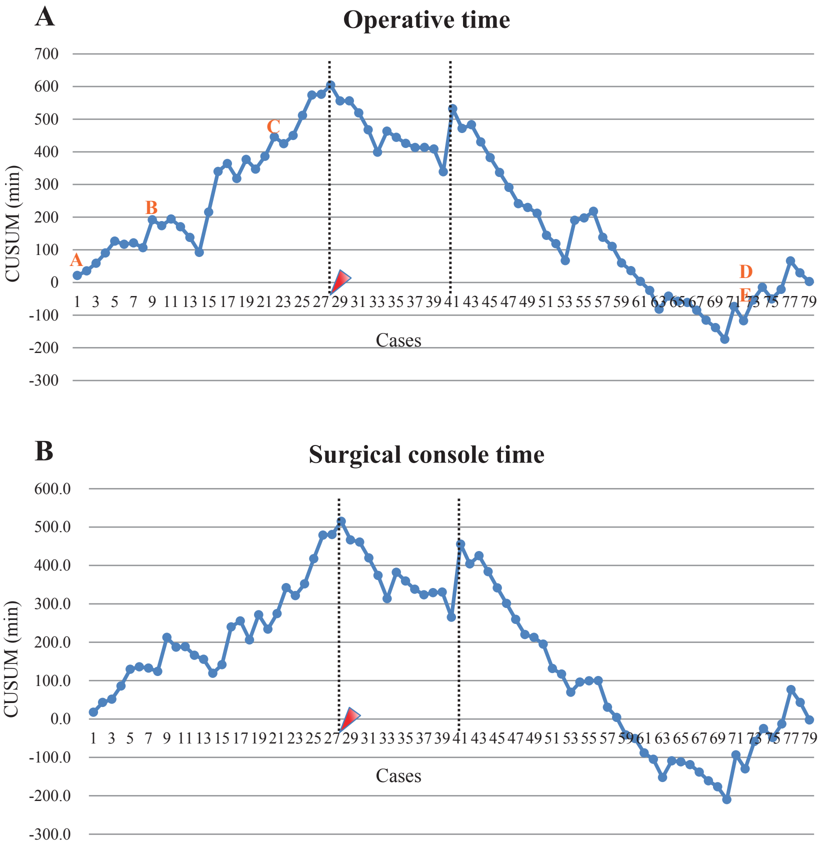


Fig. 1 The CUSUM plot for RATS lobectomy

Fig. 1A: The plot regarding Total operative time. Estimated boundary between phase I and II was the 28th case (arrowhead). A, B, C, D, and E shown in the graph indicate the first patient of each surgeon.

Fig. 1B: The plot regarding console time. Estimated boundary between phase I and II was the 28th case, the same as the total operative time (arrowhead).

Table 2 Experiences of RATS in each surgeon before the first lobectomy

Surgeon	Assistant of lobectomy	Operator of mediastinum	Assistant of mediastinum	Total
A	0	6	1	7
B	5	3	2	10
C	10	0	7	17
D	27	6	5	38
E	8	4	1	13

The numbers of operations were listed.

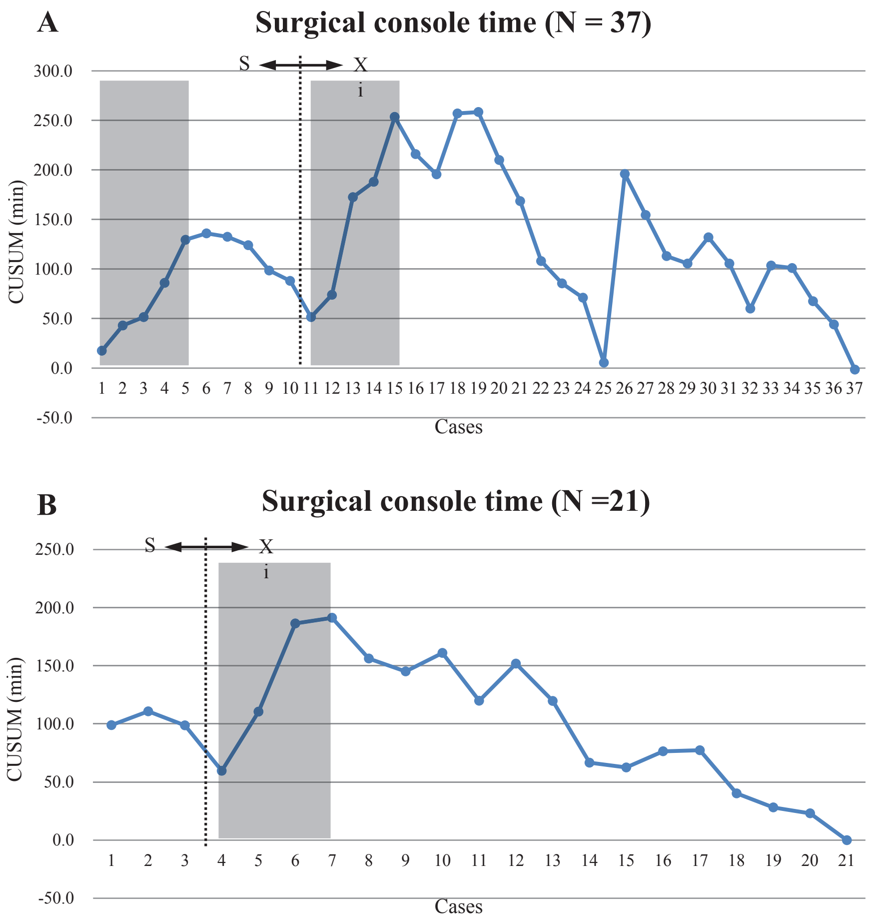
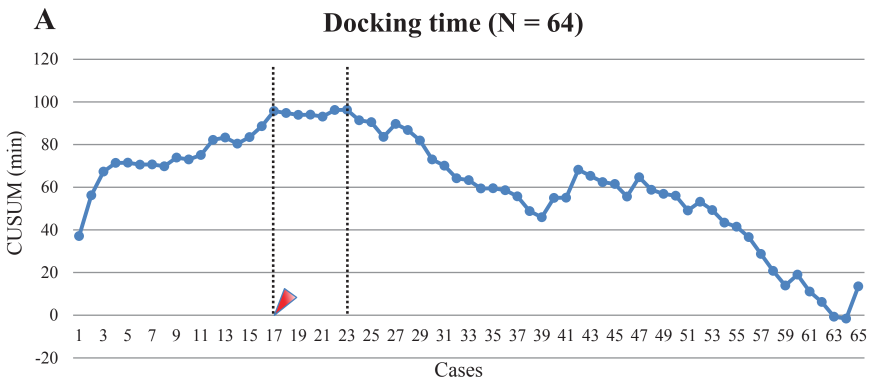


Fig. 2 The CUSUM plot for RATS lobectomy performed by one surgeon

Fig. 2A: The plot showed the results of surgeon A. Gray area indicates phase I. The Da Vinci system was changed from S to Xi, the CUSUM dropped on the way in, consequently might show the same rise again.

Fig. 2B: The plot showed the results of surgeon B.



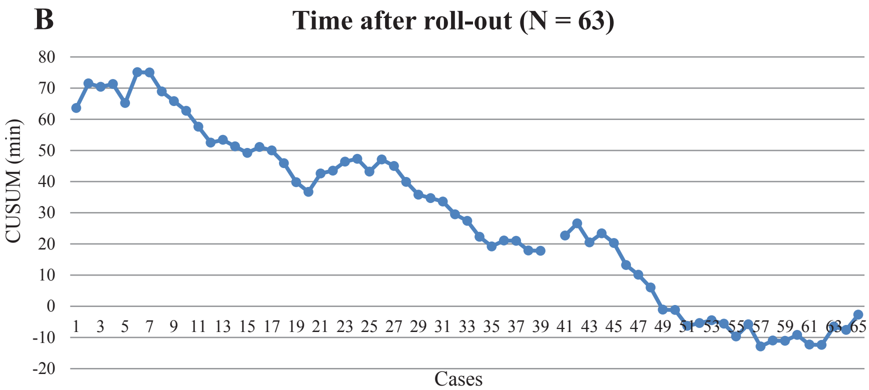


Fig. 3 The CUSUM plot for docking time and time after roll-out

Fig. 3A: The CUSUM plot for docking time. It was estimated that approximately 18 cases were required for learning (arrowhead).

Fig. 3B: The plot for time after roll-out. It did not show the typical trend and was gradually decreasing. There might not be a learning curve. Both Fig. 3A and Fig. 3B have been omitted due to insufficient data acquisition during the certain early surgeries.

Table 3 Interphase comparisons of patient characteristics and perioperative outcomes

Parameter		Phase I (N = 28)		Phase II (N = 13)		Phase III (N = 38)		*p* Value
Patient characteristics								
Age		65	(43–81)	71	(58–78)	71	(46–78)	0.16
Sex (%)	Female	19	(68)	9	(69)	20	(53)	0.36
	Male	9	(32)	4	(31)	18	(47)	
Tumor size, cm		1.3±8.3		1.1±7.4		1.7±9.8		0.15
c-stage (%)	0	3	(11)	2	(15)	2	(5)	0.67
	IA	24	(85)	11	(85)	31	(87)	
	IB	1	(4)	0	(0)	2	(5)	
Tumor location (%)	IIA	0	(0)	0	(0)	1	(3)	
	Right upper	15	(53)	5	(39)	13	(34)	0.25
	Right middle	1	(4)	3	(23)	4	(11)	
	Right lower	1	(4)	2	(15)	8	(21)	
	Left upper	4	(14)	2	(15)	7	(18)	
	Left lower	7	(25)	1	(8)	6	(16)	

Intraoperative parameters								
Operative time, minutes		205	(137–307)	164	(113–247)	157	(103–376)	0.0018
Surgical console time, minutes		164	(98–246)	125	(82–216)	129	(78–338)	0.0020
Docking time, minutes		16	(12–26)	14	(8–22)	12	(6–30)	0.0015
Time after roll-out, minutes		18	(13–84)	18	(13–25)	18	(12–25)	0.94
Blood loss, mL		29	(1–187)	10	(0–130)	5	(0–618)	0.10
Postoperative outcomes								
30-day morbidity (%)	Clavien I–II	1	(4)	0	(0)	3	(8)	0.54
	Clavien III–IV	1	(4)	0	(0)	3	(8)	
Duration of drainage, days		2	(2–11)	2	(2–3)	2	(2–11)	0.27
Length of stay, days		5	(4–12)	5	(3–6)	5	(3–13)	0.27

Continuous data are expressed as mean ± SD or median (range).
c-stage was limited to lung cancer.

Comparisons between RATS and VATS

Analysis using 224 VATS lobectomies revealed that the number of cases required as our team was approximately 70 (Fig. 4A), while VATS lobectomy by one surgeon required 35 cases (total operative time) (Fig. 4B). Thus, RATS was a technique that could be learned with fewer cases, both as a team and as an individual.

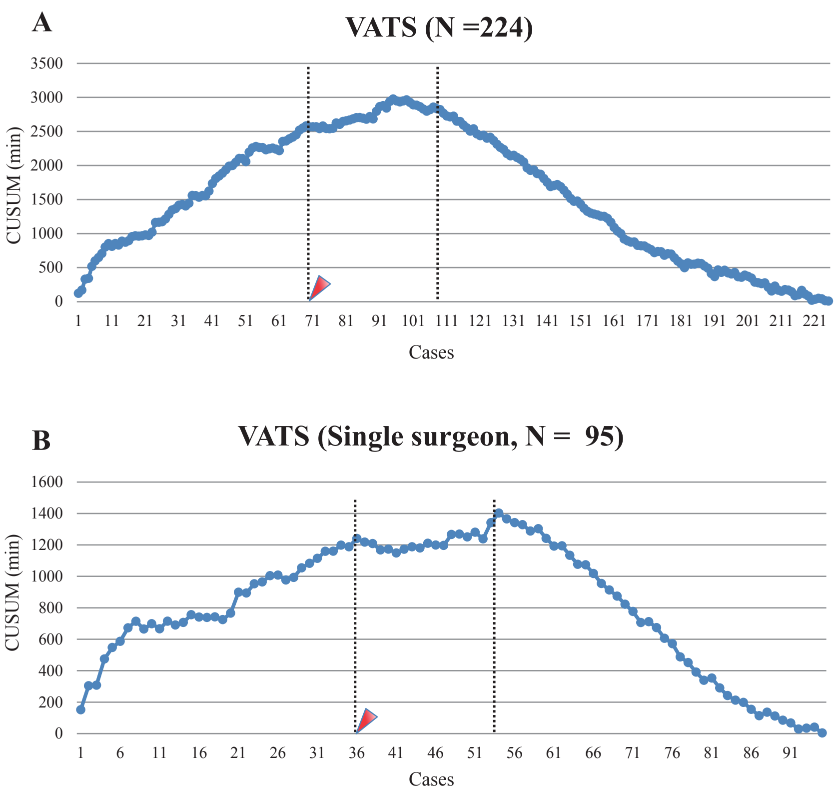


Fig. 4 The CUSUM plot for VATS lobectomy

Fig. 4A: The results for all 224 cases. Estimated boundary between phase I and II was about 70 cases (arrowhead).

Fig. 4B: The CUSUM plots limited to one surgeon. Estimated boundary between phase I and II was the 36th case (arrowhead).

DISCUSSION

RATS lobectomy has been established worldwide as a new approach to surgical intervention for lung cancer since it was first reported in 2002.[2] Several investigators have reported that RATS was feasible and safe operation, and concluded that clinical outcomes, including patient's prognosis, were comparable to conventional VATS.[3,4] With these results and the approval of national healthcare insurance in 2018 in Japan, RATS lobectomy for lung malignancy has recently been rapidly spreading. To date, minimally invasive surgery for lung malignancies has two major trends, RATS and VATS, including uniportal VATS.

The CUSUM method is a statistical index originally used to monitor the qualitative variability of industrial products. However, it has been used in various other purposes. Here is a simple example. CUSUM is used unnoticed by golfers around the world. By recording a round's score as "plus" 4 or "minus" 2, golfers use the CUSUM in a numerical sense. The golfer subtracts the par value from the actual score and adds (accumulates) the difference. Wohl et al and Chaput et al suggested that the CUSUM method should be applied to medical research, especially to the analysis of learning curves.[11,12] It was inherently difficult to objectively estimate the amount of experience required to acquire surgical techniques to some extent, and often relied on ambiguous methods. However, recently, CUSUM has been applied to the evaluation of the learning curve for surgery. There were several reports that objective evaluations were made using the CUSUM method when new technologies were introduced.[13-17]

In the field of thoracic surgery, analyses of the learning curve using the CUSUM method for uniportal VATS and RATS have been reported. Liu et al concluded that the required number was 30 in an analysis of 120 patients who underwent uniportal VATS lobectomy.[18] Similarly, Nachira et al from Italy reported that of 25 cases, and Stamenovic et al in Germany reported similar numbers of 27 cases.[19,20] For RATS lobectomy, Song et al from China reported a plateau in 32 cases using CUSUM analysis,[7] and a review article by Power et al reported that RATS lobectomy required 20 to 40 cases.[21] On the other hand, Baldonado et al questioned whether RATS lobectomy has a learning curve in an experienced thoracic surgeon.[22] The above reports were all analyzed using the record of one surgeon. In this study, analysis was performed in an operation involving multiple surgeons, including five. Thus, it represents not a personal skill but a total ability as a team of ourselves. The obtained result of 28 cases was close to previous reports of single surgeon. For simplicity, the cohort of this study was subdivided and analyzed based on a single surgeon. The result was less than the previous reports, both of which were within 10 cases, which was clearly lower than VATS. Although it was difficult to guess the reason, RATS may have less stress because RATS has more freedom of manupiration and was more similar to conventional surgery via thoracotomy.

The answer to the above may be the unique circumstances surrounding the engagement of surgeons in Japan. The first reason is that, like other hospitals, we have VATS experience before RATS. Second, each surgeon had a certain number of robotic surgery experiences before performing their first lobectomy. As shown in Table 2, all five surgeons had at least seven robotic surgeries before beginning a lobectomy. Furthermore, all but surgeon C had experienced mediastinal surgery as an operator. In Japan, staff surgeons usually participate in resident's surgery as assistants. Thus, our hospital is not special. In addition, at least 20 hours of practice using a real da Vinci and a practical test were required when acquiring a license of da Vinci system. For these reasons, it was thought that robotic lobectomy could have been learned in a very small number of cases.

What the learning of surgery is and what it can be said to have learned a technique is a very difficult issue.[21] In applying the CUSUM method, many previous reports to date have been based on the mean operative time. Time-based analysis requires that the quality of the surgery be assured. The most important purpose of lobectomy for lung malignancy is complete removal of the lesion and lymph node dissection for accurate staging, and it must be safe. Moreover, the operation can be performed without excess and deficiency and that the operation is completed in a short time were not parallel. However, it is difficult to make invisible objects into criteria for objective evaluation. Therefore, in this study, as in many previous reports, the mean operative time was used as a criterion. Zhang et al recently proposed a risk-adjusted CUSUM model with a similar analysis for RATS segmentectomy.[6] There was also a model using CUSUM score, which was less susceptible to significant outliers.[23] However, the method used in this study appeared to be the simplest and most straightforward.

There were other limitations in this study. Firstly, this study was a retrospective study in which there was a change of the Da Vinci system in the middle of the period and a change in the port location. As described above, the involvement of multiple surgeons was different from previous reports. Second, the CUSUM method had disadvantages. Specifically, the judgment between phases relies on the visual appearance. In addition, the number of patients in this study was slightly lower than in previous reports, although there is no criterion for how many cases are more appropriate. Finally, it was unclear whether the results of this study were universal. Each surgeon has some VATS experience before starting RATS, which may not be a fair comparison. Each surgeon's experience in starting a RATS lobectomy varies, and the quality of the team varies from facility to facility.

In conclusion, RATS lobectomy might be a technique that could be learned in a small number of cases compared to VATS. The results of this study might be helpful for certified surgeons in Japan who tried to get started with RATS and for establishing a learning program. However, learning curve of this new technique might depend on the quality of the team, the presence or absence of a skilled instructor, and various patient factors.

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CONFLICT OF INTEREST

The authors have declared that no conflict of interest exists.

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