

Effects of robot- and video-assisted thoracoscopic lobectomy experiences on the learning curve of lobectomy

Robot ve video yardımlı torakoskopik lobektomi deneyimlerinin lobektominin öğrenme eğrisi üzerine etkileri

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ABSTRACT

Background: This study aims to investigate the effects of robot- and video-assisted thoracoscopic lobectomy on the learning curve of lobectomy.

Methods: Between September 2013 and February 2020, the first 68 consecutive patients (28 males, 40 females; median age: 71 years; range, 33 to 86 years) who were operated for lung malignancies and scheduled for robot-assisted thoracoscopic lobectomy were retrospectively analyzed. The characteristics of the patients and operative data were analyzed, and the operation times of the first 51 cases of video-assisted thoracoscopic lobectomy were compared with those of robot-assisted thoracoscopic lobectomy performed by a single surgeon.

Results: Of the patients, 62 had primary lung cancer and six had metastatic lung tumors. The majority of primary lung cancer patients (87.1%) had an adenocarcinoma. The most common clinical stage was IA1 (30.9%). There was no emergent conversion to thoracotomy in any of the patients. The median operation time was 223.5 min, and console time was 151 min. The most common complication was an air leak. All patients were alive. Compared to video-assisted thoracoscopic lobectomy, the median operation time was significantly longer in the robot-assisted thoracoscopic lobectomy group ($p=0.0002$). Similar to the operation time learning curve of the video-assisted thoracoscopic surgery group, the operation time learning curve of the robot-assisted thoracoscopic surgery group increased from the first to ninth case (Phase 1), plateaued from the 10th to 14th case (Phase 2), and decreased from the 15th case (Phase 3). There was a statistically significant decrease in the operation time between Phase 1 and Phase 3 ($p=0.0063$).

Conclusion: The results of robot-assisted thoracoscopic lobectomy by a single surgeon show that this surgery has a longer operation time, but the perioperative outcomes are satisfactory. The learning curve of this surgery may be gradual for experienced video-assisted thoracoscopic surgeons.

Keywords: Lobectomy, lung cancer, robot, thoracoscopic surgery.

ÖZ

Amaç: Bu çalışmada robot ve video yardımlı torakoskopik lobektominin, lobektomi öğrenme eğrisi üzerine etkileri araştırıldı.

Çalışma planı: Eylül 2013 - Şubat 2020 tarihleri arasında akciğer maligniteleri nedeniyle ameliyat edilen ve robot yardımlı torakoskopik lobektomi yapılması planlanan ilk 68 ardışık hasta (28 erkek, 40 kadın; medyan yaş: 71 yıl; dağılım, 33-86 yıl) retrospektif olarak incelendi. Hastaların özellikleri ve ameliyat verileri analiz edildi ve video yardımlı torakoskopik lobektomi yapılan ilk 51 hastanın ameliyat süreleri, tek bir cerrah tarafından yapılan robot yardımlı torakoskopik lobektomi yapılanları ile karşılaştırıldı.

Bulgular: Hastaların 62'sinde primer akciğer kanseri ve altısında metastatik akciğer tümörleri mevcuttu. Primer akciğer kanserli hastaların büyük bir kısmında (%87.1) adenokarsinom vardı. En sık görülen klinik evre IA1 idi (%30.9). Hastaların hiçbirinde acil torakotomiye dönülmedi. Medyan ameliyat süresi 223.5 dk ve konsol süresi 151 dk idi. En sık görülen komplikasyon hava kaçağı idi. Hastaların tümü sağ kaldı. Video yardımlı torakoskopik lobektomiye kıyasla, medyan ameliyat süresi, robot yardımlı torakoskopik lobektomi grubunda anlamlı düzeyde daha uzundu ($p=0.0002$). Video yardımlı torakoskopik cerrahinin ameliyat süresi öğrenme eğrisine benzer şekilde, robot yardımlı torakoskopik cerrahinin ameliyat süresi öğrenme eğrisi birinci ila dokuzuncu olgu arasında artış gösterdi (Faz 1), 10 ila 14. olgu arasında plato çizdi (Faz 2) ve 15. olgudan sonra düşüşe geçti (Faz 3). Faz 1 ve Faz 3 arasında ameliyat süresinde istatistiksel olarak anlamlı düzeyde bir düşüş izlendi ($p=0.0063$).

Sonuç: Tek bir cerrah tarafından yapılan robot yardımlı torakoskopik lobektomi sonuçları bu cerrahinin ameliyat süresinin daha uzun olduğunu, ancak perioperatif sonuçların tatmin edici olduğunu göstermektedir. Bu cerrahinin öğrenme eğrisi, video yardımlı torakoskopik cerrahi konusunda deneyimli cerrahlar için kademeli olabilir.

Anahtar sözcükler: Lobektomi, akciğer kanseri, robot, torakoskopik cerrahi.

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One of recent trends in thoracic surgery is to make the surgery less invasive and, for following the trend, robotic surgical cases for malignant lung tumors have grown up steadily.^[1-3] In Japan, although robot-assisted thoracoscopic surgeries (RATSs) for malignant lung tumors, benign mediastinal tumors, and malignant mediastinal tumors were previously performed in clinical studies, the National Health Insurance has initiated to cover RATS for these tumors since 2018.^[4] For malignant lung tumors, RATS lobectomy, which presents several advantages over video-assisted thoracic/thoracoscopic surgery (VATS), has been reported to be feasible, safe, and oncologically effective. The long-term oncological outcomes of RATS lobectomy are acceptable for early non-small cell lung cancers and comparable with both open thoracotomy and VATS.^[5]

Although previous studies have shown that the steep learning curve of the RATS is superior to those of two conventional approaches, there is limited information on whether surgeons already experienced and skilled in performing VATS lobectomy would benefit from transitioning to RATS.^[6-8] With the assumption that RATS learning curve would be gradual for experienced VATS thoracic surgeons, in the present study, we aimed to investigate whether the learning curve based on the operation time (OT) of a single surgeon was correlated with the early experience of VATS and RATS by a single surgeon at a single institution and report the clinical results of RATS lobectomy by a single surgeon at a single institution.

PATIENTS AND METHODS

This single-center, retrospective study was conducted at Tokyo Women's Medical University Hospital, Department of Thoracic Surgery between September 2013 to February 2020. The first 68 consecutive patients (28 males, 40 females; median age: 71 years; range, 33 to 86 years) who were operated for lung malignancies with RATS lobectomy by a single thoracic surgeon who had accumulated experience in VATS were included. Medical data of the patients were obtained from the hospital database. A written informed consent was obtained from each patient. The study protocol was approved by the Human Ethics Committee of Tokyo Women's Medical University (June 26, 2020, No. 5637). The study was conducted in accordance with the principles of the Declaration of Helsinki.

Preoperative data included a detailed comprehensive history of the patients, the result of physical examination, the imaging data of computed tomographic scans, magnetic resonance imaging of the brain, and

positron emission tomography, and the results of cardiac evaluation and pulmonary function testing. Endobronchial ultrasound-guided transbronchial needle aspiration (EBUS-TBNA) was performed in patients suspected of having single-station N2 to pathologically diagnose N2 cases. The RATS indication was the same as the criteria of our VATS lobectomy. Inclusion criteria were as follows: (i) clinical Stage I, II, and IIIA lung cancers, which included only single station N2 in N2 diseases, a tumor being more than 7 cm in diameter in T4, and a separate tumor nodule or nodules in a different ipsilateral lobe to that of the primary tumor, (ii) the predicted patient's tolerance the resection by lobectomy, and (iii) the physiological state of the patient. Exclusion criteria were multi-station N2 disease, other T4 in inclusion criteria, and endobronchial tumors.

Resected specimens were examined histopathologically, and histological typing was performed by referring the World Health Organization/International Association for the Study of Lung Cancer Histological Classification of Lung Tumors.^[7] Each case was reclassified according to the 8th edition of the Tumor, Node, Metastasis (TNM) classification for lung cancer.^[9]

The patients' characteristics, operation data, intra- and postoperative complications, and prognoses were analyzed. The diagnosis of recurrent disease was made based on radiographic and pathological findings. Local recurrence was defined as the tumor progression within the ipsilateral hilum or mediastinum. Distant recurrence was defined as the development of tumor outside the thorax or in the contralateral lung or mediastinum. The OTs of the first 51 cases of VATS lobectomy were compared with those of RATS lobectomy performed by a single surgeon.

Operative technique

All lobectomies were performed using the daVinci® Robotic Surgery System (Intuitive Surgery, Sunnyvale, CA, USA). Most of the lobectomy procedures were performed using the Xi model, which became available at our hospital in 2018, with the exception of the first 10 cases performed on both the S and Si models.

Under general anesthesia with split ventilation using a double-lumen endotracheal tube, the patient was positioned in the lateral decubitus position on bed, which was flexed to place the hips below the chest wall and the arms perpendicular to the body. The RATS lobectomy was performed with four-port incisions and a 3-cm utility thoracotomy with an applicable wound protector without rib spreading, or a

carbon dioxide (CO₂) insufflation combined assistant port (Figure 1). For entering the pleural cavity, a small skin incision was made from 1 to 3 cm in length at anteriorly in the anterior-axillary line over the top of the fourth (for upper lobectomy) or fifth (for the other lobectomies) rib for utility thoracotomy or assistant port and, then, using the 8-mm 30° robotic camera, all the other incisions were created based on internal anatomy. An 8-mm daVinci® trocar was placed in the eighth intercostal space along the mid-axillary line for the robotic camera. The other 8-mm daVinci® trocars were placed in the eighth intercostal space along the posterior side of the tip of the scapula. Two 12-mm ports were placed on each side of the robotic camera. An anterior trocar was placed in the seventh (for upper lobectomy) or eighth intercostal space along the anterior-axillary line, and the other 12-mm trocar was placed in the eighth intercostal space along the posterior-axillary line. All four robotic arms were used. A CO₂ insufflation system was used at a set pressure of 5 to 10 mmHg in all portal RATS and, in some cases, utility thoracotomy combined the GelPOINT® Mini advanced access platform (Applied Medical, Rancho Santa Margarita, CA, USA)

or the LAPPROTECTOR™ (Hakko, Nagano) with E-Z ACCESS™ for FF0504 (Hakko). Robot staplers were inserted through a 12-mm port, and the robotic instruments were manipulated through a 12-mm port mounting a 12-8-mm reducer. Bronchial-stump coverage with a pedicled pericardial fat pad was applied to patients with uncontrolled diabetes mellitus with a latest hemoglobin A1c level of 7.4% or more over a normal level of less than 5.9%, and patients with preoperative chemotherapy, long-term steroid therapy, and immunosuppressants. Endoscopic lung biopsy was performed to diagnose indeterminate pulmonary nodules and, after intraoperative pathological examination revealed that the obtained specimen was a malignant tumor, VATS was switched to RATS. The VATS ports were utilized as the RATS ports, and the chest tubes were removed, when daily drainage volume was less than 150 mL.

Statistical analysis

Statistical analysis was performed using the JMP Pro software (version 15.0.0, SAS Institute, Cary, NC, USA) and JUSE-StatWorks/V5 (The Institute of Japanese Union of Scientists & Engineers, Tokyo). Continuous

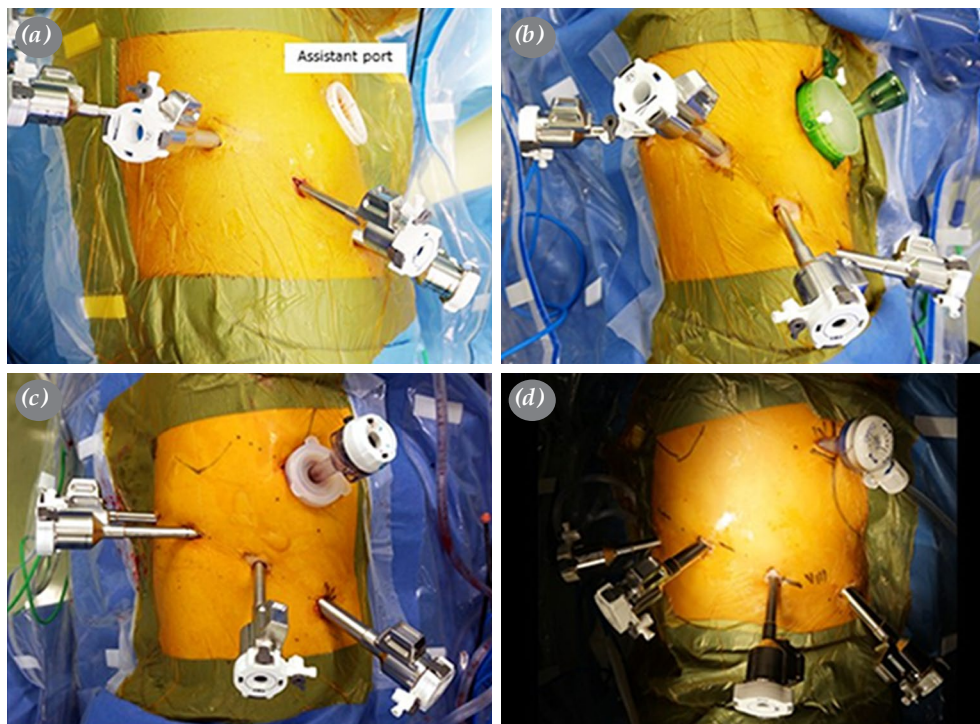


Figure 1. Intraoperative view of port placements and a utility thoracotomy for RATS. (a) Four port incisions and a 3-cm utility thoracotomy. (b) Utility thoracotomy combined GelPOINT® Mini advanced access platform. (c) Utility thoracotomy combined the LAPPROTECTOR™ with E-Z ACCESS™ for FF0504. (d) Portal RATS.

RATS: Robot-assisted thoracoscopic surgery.

variables were expressed in median (min-max), while categorical variables were expressed in number and percentage, where appropriate. To compare the groups at baseline for continuous variables, the Wilcoxon rank-sum test was used. For categorical data, the Fisher's exact test was used. The cumulative sum (CUSUM) analysis was used to examine the learning curves. In the CUSUM analysis, the mean was used as the descriptive statistic for continuous variables. The Steel-Dwass test was used to compare the OT among the three groups in RATS. In all tests, a *p* value of <0.05 was considered statistically significant.

RESULTS

Table 1 shows the characteristics of the patients. In the preoperative pulmonary function test, median functional vital capacity was 2.89 (range, 1.78 to 5.29) L, the median forced expiratory volume in 1 sec was 2.15 (range, 1.30 to 4.19) L, and median percentage

of diffusing capacity corrected for alveolar volume was 76.9%. The comorbidities were diverse, and the most frequently observed comorbidity was diabetes mellitus in six patients. Ten patients had a previous history of cancer. One patient had a kidney transplant, and other one patient was on hemodialysis. In a total of 68 RATS procedures, 62 patients had primary lung cancer, and six had metastatic lung tumors. The majority of primary lung cancer patients (55/62, 80.9%) had an adenocarcinoma. Other primary lung cancers included six squamous cell carcinomas (8.8%) and one small cell lung cancer (1.5%). Metastatic lung tumors originated from colon cancer (n=3), renal cell carcinoma (n=1), gastric cancer (n=1), and renal leiomyosarcoma (n=1). The most common clinical stage was IA1 (n=21, 30.9%). The median maximal tumor diameter was 20 (range, 4 to 65) mm.

There were 24 right upper lobectomies, 12 right middle lobectomies, 10 right lower lobectomies, 15 left

Table 1. Characteristics of the patients (n=68)

	n	%	Median	Range
Age (year)			71	33-86
Sex				
Male	28	41.2		
Female	40	58.8		
Pulmonary function				
FVC (L)			2.89	1.78-5.29
FEV _{1.0} (L)			2.15	1.30-4.19
DLCO (%)			76.9	39.9-114.8
Histology				
Primary lung cancer	62	91.2		
Adenocarcinoma	55	80.9		
Squamous cell carcinoma	6	8.8		
Small cell carcinoma	1	1.5		
Metastatic lung tumors	6	8.8		
Colon cancer	3	4.4		
Renal cell carcinoma	1	1.5		
Renal leiomyosarcoma	1	1.5		
Gastric cancer	1	1.5		
Stage				
All	62	100		
0	2	3.2		
IA1	21	33.9		
IA2	17	27.4		
IA3	11	17.7		
IB	6	9.7		
IIA	2	3.2		
IIB	3	4.8		
Maximal tumor diameter (mm)	20	4-65		

FVC: Functional vital capacity; FEV_{1.0}: Forced expiratory volume in 1 sec; %DLCO: Percentage of diffusing capacity corrected for alveolar volume.

Table 2. Operative characteristics and clinical outcomes

	n	%	Median	Range
Type of lobectomy				
Right upper lobectomy	24	35.3		
Middle lobectomy	12	17.6		
Lower lobectomy	10	14.7		
Left upper lobectomy	15	22.1		
Lower lobectomy	7	10.3		
Operative time (min)			223.5	138-331
Console time (min)			151.0	90-252
Set up time (min)			6.0	2-33
Blood loss (mL)			8	2-100
Chest tube duration (days)			4	2-14
Postoperative hospital stay (days)			8	5-32
Complications	4	5.9		
Persistent air leaks	3	4.4		
Chylothorax	1	1.5		

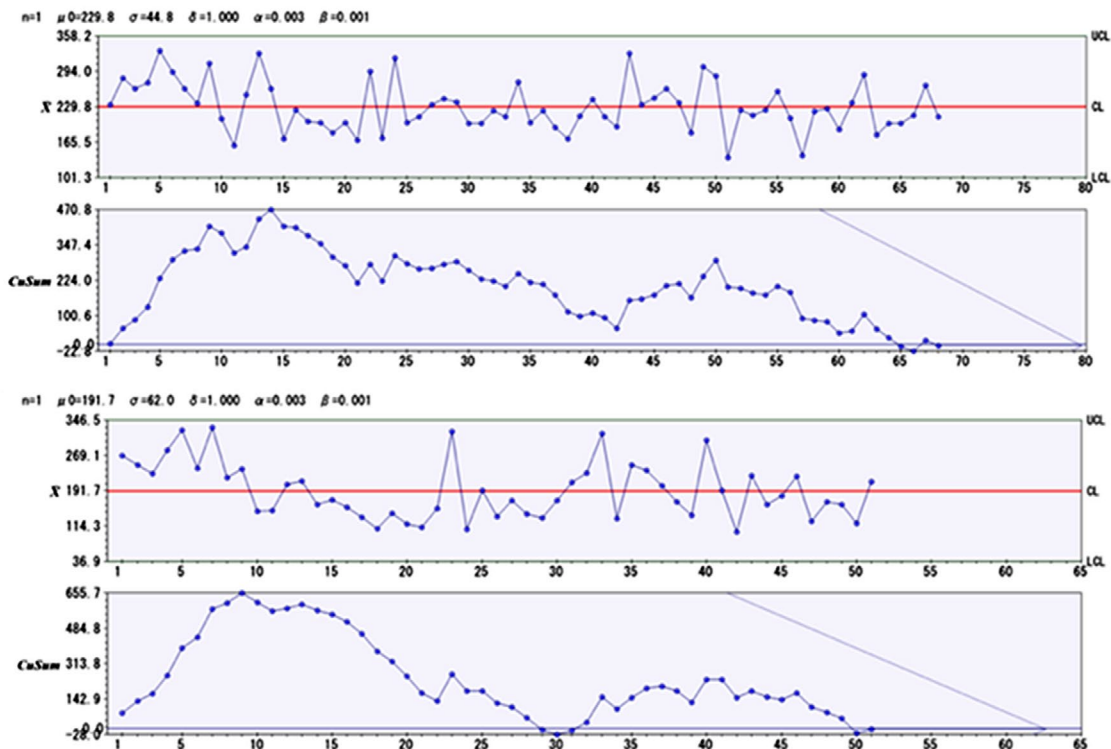


Figure 2. Cumulative sum graphs for the OTs. (a) The upper graph shows the raw data of RATS OT, and the lower graph shows CUSUM analysis graph. Data points on the learning curve graph of the OT based on CUSUM analysis increased to the 9th case, reached a plateau from the 10th to 14th case, and decreased from the 15th cases. (b) The upper graph shows the raw data of VATS OT, and the lower graph shows CUSUM analysis graph. Data points on the learning curve graph of the OT based on CUSUM analysis increased to the 9th case, reached a plateau from the 10th to 13th case, and decreased from the 14th case.

CUSUM: Cumulative sum; OTs: Operation times; UCL: Upper control limit; CL: Center line; LCL: Lower control limit.

Table 3. Patients' characteristics and outcomes in each phase of the learning curve in robot-assisted thoracoscopic surgery

	Phase 1 (Cases 1-9)			Phase 2 (Cases 10-14)			Phase 3 (Cases 15-68)		
	n	%	Range	n	%	Range	n	%	Range
Age (year)			71			71			71
Sex									
Male	5	55.6	52-78	2	40.0	57-76	21	38.9	33-68
Female	4	44.4		3	60.0		33	61.1	
Histology									
Primary lung cancer	9	100		4	80.0		49	90.7	
Metastatic lung tumors	-	-		1	20.0		5	9.3	
Stage									
All	9	100		4	100		49	100	
0	1	11.1		-	-		1	2.0	
IA1	1	11.1		2	50.0		18	36.7	
IA2	1	11.1		-	-		16	32.7	
IA3	3	33.3		-	-		8	16.3	
IB	1	11.1		2	50.0		3	6.1	
IIA	1	11.1		-	-		1	2.0	
IIB	1	11.1		-	-		2	4.1	
Maximal tumor diameter (mm)			20			24			20
Right upper lobectomy	4	44.4	12-46	2	40.0	13-32	16	29.6	4-65
Middle lobectomy	1	11.1		-	-		11	20.4	
Lower lobectomy	1	11.1		1	20.0		8	14.8	
Left upper lobectomy	1	11.1		1	20.0		13	23.2	
Lower lobectomy	2	22.2		1	20.0		6	11.1	
Operative time (min)			273.0			252.0			213.5
Console time (min)			196.0			151.0			144.5
Set up time (min)			8.0			5.0			6
Blood loss (mL)			12			10			7
Chest tube duration (days)			4			5			3
Postoperative hospital stay (days)			9			8			8
Complications	1	11.1		-	-		3	5.6	

upper lobectomies, and seven left lower lobectomies (Table 2). There was no emergent conversion to thoracotomy in any of the patients. The median OP was 223.5 (range, 138 to 331) min, median console time (CT) was 151 (range, 90 to 252) min, and median set-up time was 6 (range, 2 to 33) min. The median blood loss was 8 (range, 2 to 100) mL. None of the patients had problems related to operative bleeding requiring blood transfusion. The median chest tube duration was four (range, 2 to 14) days, and median postoperative hospital stay was eight (range, 5 to 32) days. Postoperative complications were observed in four (5.9%) patients. The most common complication was persistent air leaks for over seven days in three patients, and these patients were treated by pleurodesis. The most common complication was an air leak that lasted more than seven days in three patients, the remaining one patient had chylothorax, and all these patients were treated by pleurodesis. The hospital mortality rate was 0%. There was no re-admitted case within 30 days. Survival at a median follow-up of 11 (range, 1 to 74) months, one patient in Stage IIIA had ipsilateral pleural dissemination, another patient in Stage IIB had ipsilateral lung metastases treated with chemotherapy, and all patients were alive.

For the learning curve of a single surgeon was assessed by the CUSUM method, comparing to the experience of VATS and RATS performed by a single surgeon; i.e., the OTs of the first 51 cases of VATS and the first 68 cases of RATS (Figure 2). As for the distribution of VATS lobectomy, there were 18 upper right lobes, four right middle lobes, 22 lower right lobes, three upper left lobes, and four lower left lobes. There was no emergent conversion to thoracotomy. However, compared to RATS, the number of left-side VATS was significantly lower ($p=0.0108$). The center line (CL) was the mean value, with OT of RATS CL at 229.8 min and OT of VATS CL at 191.7 min. The OT was significantly longer in RATS than in VATS ($p=0.0002$). Based on the CUSUM graph, the following items were shown from the increase and decrease in OTs of RATS and VATS. The curve of RATS OT increased from the first to ninth case (Phase 1), plateaued from the 10th to 14th case (Phase 2), and decreased from the 15th case (Phase 3). There was a statistically significant decrease in OT between Phase 1 (mean: 275.6 min) and Phase 3 (mean: 221.0 min; $p=0.063$) (Table 3). Similarly, the curve of VATS OT increased from the first to ninth case, plateaued from the 10th to 13th case, and decreased from the 14th case. In addition, the curve of RATS CT was steep and increased from the first to fifth case, plateaued from the sixth to 14th case, and decreased from the 15th case.

DISCUSSION

The trend of thoracic surgery is to allow the surgery to be performed less invasively, particularly with the advancement of endoscopic technology, and surgical procedures have progressed remarkably in many regards.^[10-12] On the other hand, VATS is recognized to have certain limitations such as two-dimensional imaging, the limited motion range of the instrument, and the poor ergonomic placement of surgeons. Robotic surgical system is expected to compensate the drawbacks of conventional VATS and minimize the shortcomings of VATS.^[5,6] Robotic surgical systems offer fine three-dimensional high-resolution images and the improved ergonomics, which allows the surgeon to conduct intuitive maneuvers accurately and stably, and provides a greater dexterity of them over VATS that is an excellent instrument maneuverability and an additional range of arms' motion, which are not available in VATS.^[4] Therefore, the RATS has been proposed as an advanced successor to VATS.

Although reported RATS techniques have several variations in the number of robot arms, the use of CO₂ insufflation, additional utility incisions, and the locations of ports, we preferred four-port incisions combined a 3-cm utility thoracotomy, with CO₂ insufflation as needed for petite patients and patients with emphysematous change.^[6,13,14] Our assistant utility thoracotomy/port was added to standard in the fourth (for upper lobectomy) or fifth (for other lobectomies) intercostal space. As lobectomy for lung cancer was performed by VATS in almost all cases in our department, some reasons for adding a utility thoracotomy/port were found, and VATS instruments were used routinely through our VATS procedure including the aspiration of blood or fluid, easy delivery of threads and gauze by bed-side doctors, removal of specimens, and preparation for intraoperative catastrophes.^[4] Although no intraoperative catastrophe was found in 68 cases in this study, Cao *et al.*^[15] reported that 128 (7.1%) in 1,810 patients who underwent robotic anatomical pulmonary resections were converted to thoracotomy and 35 (1.9%) patients had a catastrophic event during RATS. We would continue to use the assistant utility thoracotomy/port in future cases.

Many studies confirm that robot-assisted surgeons may need no prior experience of performing endoscopic surgery for mastering a robot-assisted operation system.^[11,13,16] On the other hand, for surgeons who have an extensive experience in performing lobectomy with VATS, the learning curve may be easier to move from VATS to robotic technique.^[18] As

reported by Baldonado et al.,^[18] the learning curve of RATS by a surgeon having prior VATS experience showed no particular change point with a continuous improvement. Although various indicators including complication rates, conversion rates, OTs, and oncological outcomes are used to assess the learning curve, this study measured OTs and investigated whether the learning curve based on OT of a single surgeon was correlated with the experience in performing VATS and RATS, if there was a correlation between the learning curve and the skill of the surgeon. In the current study, the RATS required approximately 1 h more to complete the operation than VATS. As shown in Figure 2, the learning curve was divided into three phases (Cases 1-9, Cases 10-14, and Cases 15-68). In the CUSUM graph, a positive slope indicated a series of cases with above-mean OT, and a negative slope indicated a series of cases with below-mean OT. There was a statistically significant decrease in OT between Phase 1 and Phase 3. As reported by Baldonado et al.,^[18] the learning curve of RATS by a surgeon having prior VATS experience showed no particular change point with a continuous improvement. Interestingly, the learning curve of VATS was found to be similar to that of RATS, and the ideal number of RATS resection for being completed of RATS learning curve was 15 cases in this study. Although the experience in open surgeries and/or VATS is useful for performing RATS, one of the most important differences in robotic technique over other surgical techniques is that all tactile feedback is lost. The renewal of eye-hand coordination skills must be acquired in RATS procedure where all tactile feedback is lost. Furthermore, by an easy-to-use endoscope that can be operated directly by surgeons at the console for obtaining high-quality three-dimensional images at various magnifications on the monitor, one of the drawbacks of RATS, the non-tactile sensation of the operator, is compensated. Many surgeons, who are expert in VATS lobectomy, obtain information regarding the operative field through a two-dimensional monitor and visually compensate the non-tactile sensation of the operator, and yet the renewal of eye-hand coordination skills is required and must be acquired in RATS procedure. At the very least, we believe that the experience of both open surgery and VATS would certainly help surgeons to perform RATS lobectomy.^[1,16]

Nonetheless, there are some limitations to this study. This study is non-randomized and has a single-center, retrospective design with a small sample size. Therefore, the results need to be confirmed in further, multi-center, large-scale prospective, randomized

studies comparing the outcomes with those of conventional two approaches.

In conclusion, the results of robot-assisted thoracoscopic lobectomy by a single surgeon at a single institution showed that this surgery requires longer operation time, and the perioperative outcomes were able to reach a satisfactory level. By increasing the number of operations, the operation time is expected to be further shortened. The learning curve of the robot-assisted thoracoscopic lobectomy may be gradual for experienced video-assisted thoracoscopic surgeons.

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