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Defining the learning curve in robot-assisted thoracoscopic lobectomy☆

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ABSTRACT

Background: Robot-assisted thoracoscopic lobectomy has been shown to be a safe approach to pulmonary lobectomy. This study sought to define, mathematically, the learning curve for RATS lobectomy.
Methods: Patients undergoing robot-assisted thoracoscopic lobectomy at a single institution from 2010 through 2016 were considered. Covariates included patient demographics, comorbidities, operating time, length of stay, estimated blood loss, and postoperative complications. A cumulative sum analysis of operating time was performed to define the learning curve.
Results: A total of 101 patients were included. Three distinct phases of the learning curve were identified: cases 1–22, cases 23–63, and cases 64–101. There was a statistically significant difference in operating time and estimated blood loss between phases 1 and 2 ($P < .05$, $P = .016$, respectively) and between phases 1 and 3 ($P < .05$, $P = .006$, respectively). There was no statistically significant difference in comorbidities, chest tube duration, length of stay, postoperative complications, or conversion rate across the learning curve.
Conclusion: Based on operating time, the learning curve for robot-assisted thoracoscopic lobectomy is 22 cases, with mastery achieved after 63 cases. No differences in length of stay, chest tube duration, conversion rate, or complication rate were observed in the learning curve. Other factors not measured in this study may play a role in the learning process and warrant further study.

Introduction

During nearly the past 2 decades, the use of robotic technology in surgery has grown in popularity, particularly in thoracic surgery. Just as thoracoscopic surgery gained acceptance in the 1990s, robotic-assisted surgery has now been shown to be both technically feasible and oncologically sound.[1–4] The advantages of the use of robotic technology compared to thoracoscopic surgery are 3-dimensional visualization, enhanced maneuverability in small spaces, and the ease of the hilar and mediastinal dissection.[5] Disadvantages include the lack of haptic feedback, increased cost, and increased operative time.[6] Specifically, the use of robotic technology in the operating room has been associated with a learning curve across multiple surgical disciplines and procedures, including prostatectomy,[7] gastrectomy,[8,9] Roux-en-Y gastric bypass,[10] intraoperative cholangiography,[11] and rectal cancer resection.[12–15] The learning curve in pulmonary lobectomy has been studied as well[2,16]; however, the definition of a learning curve in these analyses was not as statistically rigorous as in the studies of other robotic procedures. Specifically, these studies did not use a cumulative sum analysis (CUSUM), which is a statistical technique to study deviation from a group mean or target value,[17,18] and is used to identify trends that are not discernible with other statistical approaches. This study aimed to define the learning curve for robotic-assisted thoracic surgery (RATS) lobectomy using the CUSUM technique.

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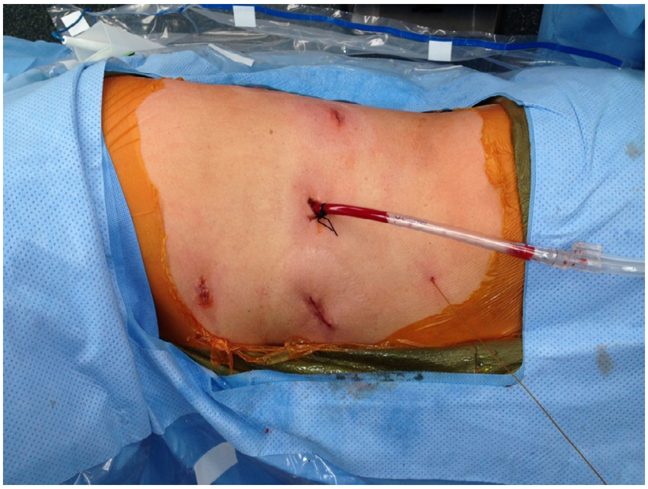

Fig. 1. Incision strategy after successful RAL-4 left upper lobectomy. The 4 small arrows indicate robotic trocar sites: arrow 1, typically in the 5th or 6th intercostal space; arrow 2, typically in the 8th or 9th intercostal space (chest tube placed through this incision); arrow 3, typically in the 9th or 10th intercostal space; arrow 4, typically in the 8th or 9th intercostal space (incision not visible, but 3 fingerbreadths lateral to the spinous process). The larger hatched arrow indicates bedside assistant utility incision, typically in the seventh or eighth intercostal space. The additional catheter is an intrathoracic, extrapleural pain catheter.

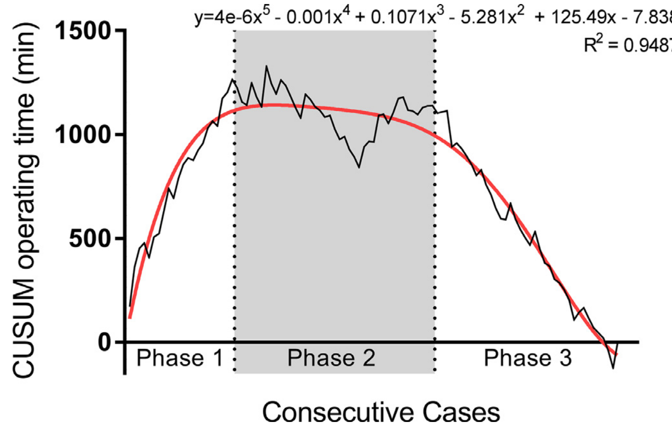

Fig. 2. CUSUM analysis with fifth-order regression showing 3 distinct phases of the learning curve.

Methods

Patient selection

All patients undergoing RATS lobectomy at a single academic medical center from January 2010 through May 2016 were considered for inclusion in the study. Patients were excluded if they underwent a right middle lobectomy, as this procedure is considered technically easier and may have biased the results in favor of a shorter learning curve. For the purposes of the CUSUM analysis, patients were also excluded if they were converted to an open procedure. Covariates included patient age, sex, Charlson comorbidity score, pathologic T stage, operative time (the time from incision to the commencement of the lymph node dissection), estimated blood loss (EBL), duration of chest tube drainage, length of stay (LOS), postoperative complication rate, and conversion rate. Conversions were additionally classified as emergent and nonemergent. Postoperative complications were defined by the Common Terminology Criteria for Adverse Events version 4.0.[19]

Operative details

A 5-incision strategy was employed for the performance of robotic lobectomies using all 4 arms of the Intuitive Surgical daVinci Si system. From a nomenclature standpoint, the Robot-Assisted Lobectomy-4 (RAL-4) was the surgical approach employed.[20] The 4 arms accommodated 3 surgical instruments (8 mm incisions) and the camera (12 mm incision; Fig. 1). The additional fifth incision (3 cm), was employed as the assistant's port as well as the port through which the resected lobe was removed. The camera incision typically was placed in the ninth intercostal space in the midaxillary line. The anterior incision typically was made in the fifth or sixth intercostal space, inferior to the visualized hilum. The posterior incisions were made such that 2 surgical instruments were placed posteriorly, typically in the 10th or 11th intercostal space in a line congruent with 2 fingerbreadths posterior to the tip of the scapula and in the eighth or ninth intercostal space in a line congruent with 3 fingerbreadths lateral to the spinous process. The assistant's incision was made in the anterior axillary line typically in the seventh intercostal space in line with the major fissure. Through this incision, a wound retractor was placed.

Once the incisions were made and the robotic trocars placed, the robot was docked over the head of the patient approximately 15° anterior to the head of the patient. The sequence of operative steps used for the lobectomies was performed in a manner similar to that employed for the video-assisted thoracoscopic surgery (VATS) approach. The only modification was that opening the fissure was a priority early in the operation, generally before the division of the vascular structures. The major exception was that for the right upper lobe resections, the fissure was opened after the division of the upper lobe branch of the superior pulmonary vein and the truncus anterior branch of the pulmonary artery in an effort to expose the posterior ascending branch of the pulmonary artery.

Cumulative sum analysis

A CUSUM analysis was performed for the adjusted operative time variable. This methodology[9,21] allowed for the detection of small changes in performance measures that may have been undetectable using other measures. The CUSUM statistic for the first case was calculated by comparing the operative time to the average operative time for the case series. The CUSUM statistic for the second case was added to the CUSUM for the previous case. In this way, a positive slope indicated a series of cases with above-average operative time, and a negative slope indicated a series of cases with below-average operative time.

Statistical analysis

Bivariate analysis was performed using analysis of variance and Wilcoxon nonparametric tests for continuous variables and χ^2 tests for categorical variables. The CUSUM analysis was fitted to a fifth-order polynomial. This regression line was used to divide the learning curve into 3 phases. Bivariate analysis was performed using SAS version 9.4 (SAS Institute, Cary, NC). CUSUM analysis was performed in R (R Foundation for Statistical Computing, Vienna, Austria). This study was approved by the Yale Institutional Review Board and a waiver of informed consent was received.

Results

Patient cohort

Of the 116 consecutive patients identified, 101 patients met criteria for inclusion in the analysis. A total of 7 patients were

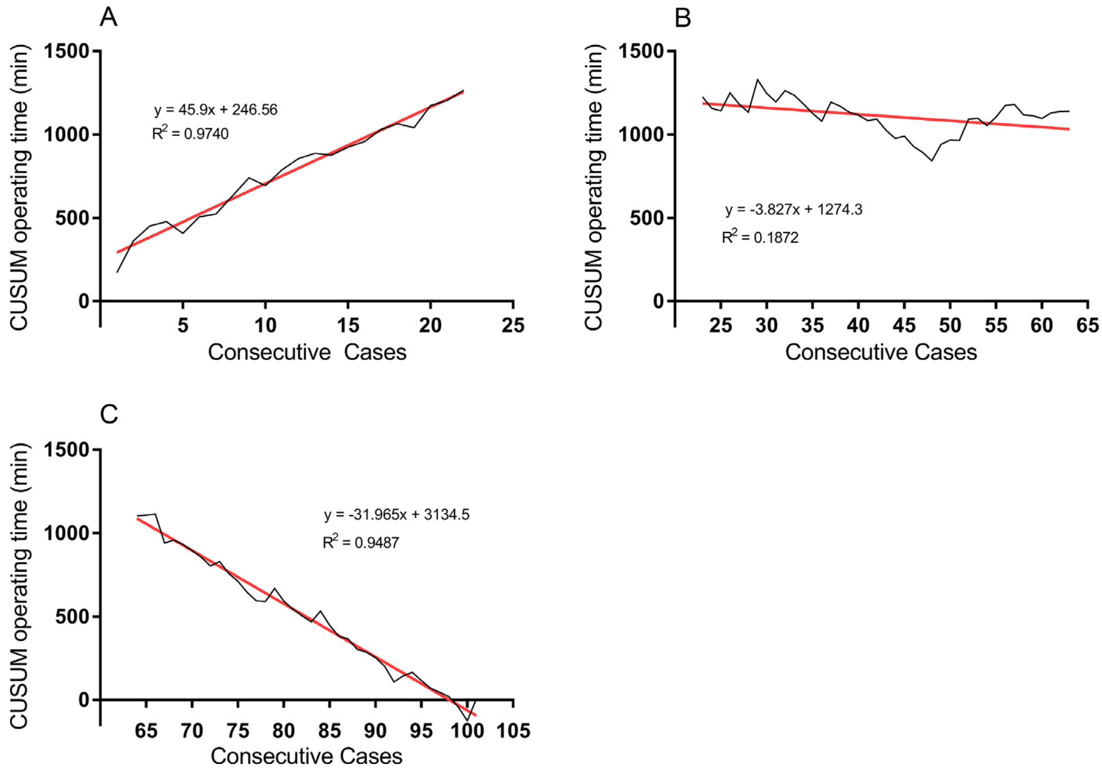

Fig. 3. Linear regression analysis for each phase of the learning curve; (A) phase 1, (B) phase 2, (C) phase 3.

excluded for having undergone a right middle lobectomy, and 8 patients were excluded for having undergone conversion to open procedure. The mean age was 69.2 ± 11.0 and 52% (53/101) patients were female. The overall complication rate was 33% (33/101).

Definition of the learning curve

Data from the CUSUM analysis of adjusted operative time was fitted to a fifth order polynomial, as shown in Fig. 2. Based on this figure, the learning curve was divided into 3 phases (cases 1–22, cases 23–63, and cases 64–101). The 3 phases of the learning curve are shown individually in Fig. 3.

Comparison of learning curve phases

The Table 1 shows a comparison of patient demographics and perioperative variables for each of the 3 phases. There was no statistical difference in age, gender, pathologic T stage, or Charlson score between the 3 phases. There was a statistically significant decrease in operative time between phases 1 (256 ± 65 minutes) and 2 (195 ± 62 minutes; $P = .0002$), as well as between phases 1 and 3 (168 ± 53 minutes; $P < .0001$). There was a trend toward a significant decrease in operative time between phases 2 and 3 ($P = .0504$). There was also a significant reduction in estimated blood loss between phases 1 (200 mL, interquartile range [IQR] 150–300 mL) and 2 (150 mL, IQR 75–200 mL; $P = .0219$) and between phases 1 and 3 (150 mL, IQR 100–150 mL; $P = .0096$). There was no difference in EBL between phases 2 and 3 ($P = .8113$). Despite the differences in operative time and EBL, there was no difference in chest tube duration, LOS, overall complication rate, or conversion rate between the 3 phases. Complications were further divided using the Common Terminology Criteria for Adverse Events version 4.0 terminology, where class I and II complications were considered minor complications, and classes III through V were considered major complications. There was no statistically significant difference in minor or major complications throughout the learning curve. Conversion rates in phases 1, 2, and 3 were 12% (3/25), 9% (4/45), and 3% (1/39), respectively. Of note, there were 2 emergent conversions, 1 each in phases 1 and 2. There were no intraoperative or immediate perioperative mortalities, and the 30-day and 90-day incidence of mortality was 0%.

The outcome measures of operative time, LOS, and complications were compared to the VATS lobectomies done at the same institution over a similar time period of 2008 to 2014. Compared to VATS, RATS lobectomies had longer mean operative times (319 min vs 253 min; $P < .001$), similar median LOS (4 days vs 3 days; $P = .74$), and similar complication rates (40% vs 32%; $P = .29$).

Discussion

This analysis represents the first robust quantification of the learning curve for robotic lobectomies using the CUSUM method. It demonstrated a learning curve of approximately 22 operations, with mastery achieved after 63 operations. This is approximately consistent with prior work showing a learning curve of approximately 20 cases, though these recommendations were based on either a composite endpoint using operative time, surgeon comfort, and mortality[16,22]; perioperative mortality alone[23]; or expert consensus.[24] Other larger series of robotic pulmonary resections[25,26] have not formally commented on the learning curve, though in 1 study, technical modifications were made after 62 cases, after which there were reductions in operative time and conversion rate.[26] This analysis presents a more rigorous and objective definition of the learning using a widely accepted statistical technique for measuring subtle changes in a measured outcome over time.

The CUSUM method, first described in detail in 1954,[27] has been utilized in the health care industry for numerous decades as a tool for monitoring quality control, to monitor the outbreak of disease, and to establish proficiency at a new skill.[17] The strength of the CUSUM method lies in its ability to detect small deviations from an established baseline, whether that is a predefined

Table 1
Patient characteristics and outcomes in each phase of the learning curve.

	Phase 1 (Cases 1–22)	Phase 2 (Cases 23–63)	Phase 3 (Cases 64–101)
Age, y	65.8 ± 12.2	69.5 ± 13.1	70.8 ± 6.9
Percent female	45.5% (10/22)	43.9% (18/41)	65.7% (25/38)
Charlson score	2.4 ± 2.1	2.0 ± 2.2	1.8 ± 2.1
T stage 1	36% (8/22)	44% (18/41)	58% (22/38)
T stage 2	27% (6/22)	27% (11/41)	32% (12/38)
T stage 3	9% (2/22)	12% (5/41)	0% (0/38)
T stage 4	5% (1/22)	2% (1/41)	0% (0/38)
T stage n/a	23% (5/22)	15% (6/41)	11% (4/38)
Adjusted OR time	256 ± 65[‡§]	195 ± 62	168 ± 53
EBL[*]	200 (150–300)[‡§]	150 (75–200)	150 (100–150)
Chest tube duration[†]	2.5 (2–3)	3 (2–7)	3 (2–5)
LOS[†]	3.5 (2–5)	4 (2–7)	4 (3–6)
Complication rate	27% (6/22)	44% (18/41)	24% (9/38)
Minor complications	27% (6/22)	41% (17/41)	18% (7/38)
Major Complications	0	2% (1/41)	5% (2/38)
Conversion rate	12% (3/25)	9% (4/45)	3% (1/39)

[*] in milliliters, median and interquartile range.
[†] in days, median and interquartile range.
[‡] statistically significant between phase 1 and phase 2.
[§] statistically significant between phase 1 and phase 3OR = operative.

standard or relative to the data at hand. In this case, since there was no validated benchmark for operative time, the baseline for the CUSUM analysis was set at the mean operating time as was done in other learning-curve analyses.[9,21] This way, the interpretation of the learning curve is relative to the mean operating time. A positive slope indicates a series of cases with above-average operating time, whereas a negative slope indicates a series of cases with below-average operating time. When considering an individual surgeon's experience, an upward slope represents the learning phase, a flat slope represents a phase of continuing development, and a downward slope represents mastery. In this analysis, we identified these 3 distinct phases of the learning curve by identifying inflection points in the CUSUM curve. The learning phase spanned the first 22 cases, followed by a continuing development phase of 41 cases, and mastery during the final 38 cases.

While decreasing operative time is a useful objective measure of the learning curve that is accepted across surgical disciplines and is correlated with experience, it does have limitations. While operative time encompasses many aspects of the operation, including the technical ability of the surgeon as well as the proficiency of the entire operating team, operative time alone does not reflect specific intraoperative decision making or complications, and thus may not reflect the true measure of surgeon safety, which is of paramount importance. To this end, other perioperative outcomes such as blood loss, conversion rate, and complication rate were analyzed. There was a significant decrease in estimated blood loss after the initial learning phase compared to the latter 2 phases, another indicator of the presence of a learning curve. There was no significant decrease in conversion rate or complication rate, though there was a trend toward a lower conversion rate throughout the study period.

It is interesting to note the similarities in the adaptation of robotic technology compared to the adaptation of VATS technology. An expert opinion suggested that 50 VATS lobectomies were needed to become proficient with the procedure.[28] In a survey of international VATS experts, the majority of respondents estimated the initial learning curve for VATS was 50 cases,[29] with the performance of at least 20 cases annually to maintain proficiency. Yet another study suggested the learning curve for VATS to be between 100 and 200 cases.[30] In considering why the learning curve for RATS has been consistently demonstrated to be shorter than for VATS, it may be that the transition from performing open surgery to any minimally invasive approach requires more skill acquisition than transitioning from one minimally invasive approach (ie, VATS) to a different minimally invasive approach (ie, RATS).

The existence of a learning curve for the performance of robotic lobectomy gives merit to the idea of close monitoring of outcomes when starting to perform these cases. This also lends credence to the idea of developing a robotic training program for surgical trainees to ensure optimal outcomes. The Fundamentals of Robotic Surgery curriculum was proposed in 2013 and included stakeholders from a wide variety of surgical professional societies as well as the Accreditation Council of Graduate Medical Education.[31] In addition, the Society of American Gastrointestinal and Endoscopic Surgeons produced a consensus statement concerning the need for improved training and hospital credentialing mechanisms with respect to robotic surgery, recognizing the lack of guidelines in this area.[32]

This study is retrospective in nature and thus is subject to the biases of all retrospective studies, particularly selection bias, as the operative approach chosen was at the discretion of the surgeon. Furthermore, this was a single institution, single-surgeon series, and thus the specific operative times and learning rates may not be generalizable. Specifically, the surgeon in this series had considerable experience with VATS prior to beginning RATS (30 cases per year in the preceding 2 years). Therefore, for better or for worse, the results may not apply to surgeons without this experience who move from open surgery to robotic surgery. In fact, the sequence of operative steps employed for a specific lobe evolved over the course of performing thoracoscopic lobectomies. These steps were perceived to facilitate the safe teaching of the steps of a lobectomy while maximizing safety. Consequently, outcomes such as operative time may have been longer than those of other experienced thoracic surgeons.

This analysis objectively defined 3 distinct phases of the learning curve for the performance of robotic-assisted pulmonary lobectomy in this single-surgeon series, with a learning phase of 22 cases, followed by a continuing development phase of 41 cases, and finally a mastery phase of 38 cases. With the exception of EBL, there was no difference in perioperative outcomes between the 3 phases. This supports the use of the CUSUM method to monitor outcomes of robotic surgery and lends further support to the adaptation of formalized robotic training and credentialing procedures. Further study is needed to establish appropriate quality benchmarks for continuously monitoring safety in robotic procedures, particularly after the initial learning phase.

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