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Original

Surgical risk score as a useful predictor for postoperative complications in lung cancer patients

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Abstract

The estimation of physiological ability and surgical stress (E-PASS) is one proposed evaluation system for postoperative morbidity and mortality. Although less invasive video-assisted thoracic surgery (VATS) is widely used as a surgical approach for lung cancer, prediction of postoperative complications is still unclear. In this study, we validate the utility of modified E-PASS (mE-PASS), using the comprehensive risk score fixed (CRSf) that has been designed and specialized for complete-VATS (c-VATS). A total of 444 eligible patients who underwent c-VATS lobectomy for lung cancer were retrospectively analyzed. They were divided into two groups: the CRSf-high (n=175) and CRSf-low (n=269) groups. The cutoff value for the CRSf was obtained using receiver operating characteristic curve analysis. We calculated the mE-PASS scores and evaluated the correlation between the CRSf and the occurrence of postoperative pulmonary and cardiac complications (PCCs) in the two groups. The occurrence of PCCs was significantly higher in the CRSf-high group. Logistic regression analysis demonstrated that the mE-PASS CRSf score was an independent predictor of PCCs after c-VATS (odds ratio: 3.92, $p < 0.001$). The mE-PASS CRSf was useful for predicting the occurrence of PCCs in patients with lung cancer undergoing c-VATS lobectomy.

Key words : *postoperative complications, surgical risk score, lung cancer surgery, VATS, lobectomy*

I. Introduction

The number of patients with lung cancer is increasing annually, and lung cancer is the leading cause of cancer-related deaths worldwide. Surgery remains the best curative treatment in patients with resectable lung cancer; however, postoperative complications are observed in several populations. In such populations, determining the preoperative risk score for postoperative complications might be important not only for informed consent, but also to contribute to improvement in surgical outcome by risk assessment following

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postoperative management. Previous reports have shown that postoperative complications were an independent predictor of 5-year cancer-specific survival in patients who underwent lobectomy for stage I non-small cell lung cancer (NSCLC) [1].

In 1999, the estimation of physiological ability and surgical stress (E-PASS) scoring system was generated by Haga et al as a predictive score for postoperative morbidity and mortality [1, 2]. E-PASS comprises a physiological risk score (PRS), indicating physiological function provided to the patient, and a surgical stress score (SSS), representing surgical invasiveness items. A comprehensive risk score (CRS) is calculated from the PRS and SSS. As the CRS increases, the post-operative morbidity and mortality increase [2, 3]. Since its introduction, the validity and usefulness of E-PASS have been reported in several areas, such as gastroenterological surgery [4], orthopedics [5], vascular surgery [6], and thoracic surgery [7, 8]. However, the E-PASS scoring system is not able to preoperatively predict risks, such as occurrence of postoperative morbidity, because the SSS includes intraoperative factors. Recently, E-PASS has been further improved, and the modified E-PASS (mE-PASS) was proposed in 2011 [9]. mE-PASS uses the SSS-fixed (SSSf), which is the fixed value for each surgical procedure, as an indicator of surgical severity instead of the SSS. This has enabled the preoperative prediction of postoperative morbidity and mortality for each surgical procedure. mE-PASS is correlated with the occurrence of postoperative complications, and it is useful for the prediction of postoperative death. mE-PASS is now widely known, and it has been reported in a multicenter prospective study of gastrointestinal surgery [10].

In recent years, video-assisted thoracic surgery (VATS) pulmonary lobectomy has become a well-established approach and widespread therapeutic method for treating NSCLC [11]. VATS has several advantages over conventional open thoracotomy, including less pain, less impairment of the shoulder girdle, shorter hospital stay, and better preservation of pulmonary function in the early period after surgery [12-15]. Complete-VATS (c-VATS) performed with a small incision is even less invasive, because it is possible to minimize destruction of the chest wall, including the accessory respiratory muscle. Although c-VATS is widely performed in NSCLC, preoperative predictive risk score assessment, especially with mE-PASS, has not been studied thus far.

In this study, we retrospectively evaluated and validated the predictive ability of mE-PASS for postoperative complications in patients with NSCLC who underwent pulmonary lobectomy by c-VATS.

II. Materials and methods

1. Patients

The medical records of 444 consecutive patients who underwent c-VATS pulmonary lobectomy and mediastinal lymph node dissection for primary lung cancer between January 2013 and December 2017 at our institute were retrospectively reviewed. This study was approved by the institutional review board of the Ethics Committee of Iwate Medical University School of Medicine (permit number: MH2018-047); we enrolled patients who did not reject the registration by the opt-out procedure. No patients received preoperative chemotherapy or radiation therapy, and cases of emergency surgery were excluded from this study. Tumor histology was done classified following the World Health Organization (WHO) criteria, and postoperative staging was according to the international TNM classification for lung cancer (7th)[16]. All patients underwent a complete preoperative pulmonary evaluation, and predictive postoperative pulmonary function was calculated in the manner reported previously[17]. Predictive vital capacity (Pred-VC) was calculated as:

Pred-VC = measured vital capacity × (19 - number of resected segments)/19

The number of segments was 3 for the right upper lobe, 2 for the middle lobe, 5 for the right lower lobe, 5 for the left upper lobe, and 4 for the left lower lobe. Predictive forced expiratory volume in 1 second (Pred-FEV_1) and predictive percentage of predicted diffusing capacity of the lung for carbon monoxide (Pred-%D_{LCO}) were calculated in the same manner.

2. Surgical procedure

Patients were intubated using either a left- or right-sided double-lumen endotracheal tube. A c-VATS pulmonary lobectomy via the classical three-incision method was performed with monitor vision only. The first 3-cm incision was made in the sixth intercostal space at the mid-axillary line, and then 5 mm of the flexible thoracoscope (ENDOEYE FLEX, LTF-S190-5, Olympus, Tokyo, Japan) was inserted. Systematic complete hilar and mediastinal lymph node dissection was performed in all cases. After completing the procedure, a single straight chest tube (Blake®, 19Fr, Ethicon, Somerville, NJ, US) was placed in the posterior apex and connected to the chest drainage system, to which −5 cmH_2O of suction was applied on the day of surgery.

3. E-PASS/mE-PASS scoring system

Table 1 shows the E-PASS and mE-PASS scoring systems. As reported previously, the E-PASS scoring system consists of six patient factors and three surgical factors[2, 3].

The former variables form the PRS, and the latter variables comprise the SSS. Taken together, the PRS and SSS make up the CRS. The specific SSSf value applied to c-VATS was calculated from the median SSS value of 444 eligible patients. The mE-PASS using the CRS fixed (CRSf) was designed by substituting the SSSf for the SSS[9], which was determined to be – 0.175. Therefore, the mE-PASS applied for c-VATS pulmonary lobectomy was:

"CRSf = 0.052 + 0.58 × (PRS) – 0.14525."

Diabetes mellitus was defined according to the WHO criteria. Performance status index was defined as by the Japanese Society for Cancer Therapy, and is the same as that as defined by the Eastern Cooperative Oncology Group.

4. Postoperative complications

The end points of this study were the occurrence of postoperative complications within 30 days after surgery and postoperative hospital mortality.

Postoperative complications in this study were evaluated as pulmonary and cardiac complications (PCCs) of Clavien-Dindo classification grade II or higher[18]. Pulmonary complications included pneumonia, prolonged air leak, interstitial pneumonitis, atelectasis, bronchopleural fistula, bronchial asthma, atelectasis, and acute respiratory distress

Table 1. Definition of modified E-PASS

E-PASS

1. Preoperative risk score (PRS)

$$= -0.0686 + 0.00345X_1 + 0.323X_2 + 0.205X_3 + 0.153X_4 + 0.148X_5 + 0.0666X_6$$

X_1, age; X_2, presence (1) or absence (0) of severe heart disease; X_3, presence (1) or absence (0) of severe pulmonary disease; X_4, presence (1) or absence (0) of diabetes mellitus; X_5, performance status index (0-4); X_6, American Society of Anesthesiologists physiological status classification (1-5).

Severe heart disease was defined as heart failure of New York Heart Association Class III or IV, or severe arrhythmia requiring mechanical support. Severe pulmonary disease was defined a condition with a% VC <60% and/or a %FEV_1. <50%. Performance status index was based on the definition by Japanese society for cancer therapy.

2. Surgical stress score (SSS)

$$= -0.342 + 0.0139X_1 + 0.0392X_2 + 0.352X_3$$

X_1, blood loss/body weight (g/kg); X_2, operation time (h); X_3, extent of skin incision.

(0 = minor incision for laparoscopic or thoracic surgery (including scope-assisted surgery); 1 = laparotomy or thoracotomy alone; 2 = both laparotomy and thoracotomy

3. Comprehensive risk score (CRS)

$$= -0.328 + 0.936\ (PRS) + 0.976\ (SSS)$$

mE-PASS

4. Comprehensive risk score fixed (CRSf)

$$= 0.052 + 0.58\ (PRS) + 0.83\ (SSSf)$$

Values indicate mean (SD) or number (%).
SEH, subependymal hemorrhage; PVL, periventricular leukomalacia; CLD, chronic lung disease.

syndrome [19]. Prolonged air leak was defined as air leakage lasting 7 days or more [20]. Cardiac complications included atrial fibrillation, hypotension, and bradycardia [21]. Other complications, such as surgical site infection, drug eruption, and mental disorder were excluded in this study.

5. Statistical analysis

JMP 14.0 (SAS Institute, Inc., Cary, NC, US) was used for statistical analysis. Pearson's chi-square test was used to compare categorical variables, and continuous variables were compared using Student's *t*-test and a non-parametric test. Multivariate analysis was performed using logistic regression analysis, and the odds ratios (OR) and 95% confidence intervals were calculated. To determine the cutoff value for each variable that gave the maximum sensitivity and specificity for the prediction of PCCs in this study population, conventional receiver operating characteristic (ROC) curve analysis was performed. However, since the cutoff value is determined based on this study population, the use of the cutoff value was limited to this study. Differences between groups were considered significant at $p < 0.05$. Continuous data of the normal distribution were expressed as mean ± standard deviation. Categorical data are shown as counts and percentage.

Table 2. Patients characteristics

	CRSf-low n=269	CRSf-high n=175	p-value
Age	68.23 ± 9.18	73.65 ± 7.11	< 0.001
Gender			
Male	138 (51.3)	73 (75.3)	< 0.001
Female	131 (48.7)	24 (24.7)	
Height (cm)	159.00 ± 10.91	158.91 ± 7.84	0.604
BMI (kg/m^2)	23.05 ± 3.29	23.64 ± 2.96	0.056
Brinkman index	472.46 ± 535.35	638.40 ± 568.20	< 0.001
Medical history			
Hypertension	104 (38.7)	59 (60.8)	< 0.001
Diabetes mellitus	1 (0.4)	30 (30.9)	< 0.001
COPD	4 (1.5)	24 (24.7)	< 0.001
IP	9 (3.3)	10 (10.3)	< 0.001
Ischemic heart disease	3 (1.1)	19 (19.6)	< 0.001
Heart failure	1 (0.4)	1 (1.0)	0.759
ASA grade			
I	69 (25.7)	1 (0.6)	< 0.001
II	193 (71.7)	61 (34.9)	
III	7 (2.6)	113 (64.6)	
IV	0 (0.0)	0 (0.0)	
PS			
0	269 (100.0)	174 (99.4)	0.215
1	0 (0.0)	1 (0.6)	
Predictive postoperative value			
Predictive VC (L)	2.51 ± 0.71	2.35 ± 0.57	0.243
Predictive FEV_1 (L)	1.89 ± 0.53	1.67 ± 0.41	< 0.001
Predictive $\%D_{LCO}$ (%)	93.69 ± 25.87	86.15 ± 24.30	0.001
pStage			
0	12 (4.5)	3 (3.1)	0.399
IA	130 (48.3)	43 (44.3)	
IB	53 (19.7)	22 (22.7)	
IIA	20 (7.4)	10 (10.3)	
IIB	11 (4.1)	6 (6.2)	
IIIA	35 (13.0)	11 (11.3)	
IIIB	1 (0.4)	0 (0.0)	
IV	7 (2.6)	2 (2.1)	
Surgical procedure			
RUL	74 (27.5)	50 (28.6)	0.659
RML	26 (9.7)	9 (5.4)	
RLL	70 (26.0)	52 (31.1)	
LUL	53 (19.7)	30 (18.0)	
LLL	39 (14.5)	28 (16.8)	
RUML	2 (0.7)	2 (1.2)	
RMLL	5 (1.9)	4 (2.4)	
Operation time (hr)	4.00 ± 1.11	4.23 ± 1.23	0.046
Blood loss (mL)	49.78 ± 57.39	50.42 ± 47.00	0.903

Value are mean ± SD or n (%)
ASA,american society of anesthesiologists; BMI,body mass index; COPD,chronic obstructive pulmonary disease; CRSf,comprehensive risk score fixed; $\%D_{LCO}$,percentage of predicted diffusing capacity of the lung for carbon monoxide; FEV_1, forced expiratory volume in 1 second; IP, interstitial pneumonia; LLL, left lower lobe; LUL, left upper lobe; PS, performance status; RLL, right lower lobe; RML, right middle lobe; RMLL, right middle lower lobe; RUL, right upper lobe; RUML, right upper middle lobe; SD, standard deviation; VC, vital capacity.

Table 3. Detail of postoperative complications

Postoperative complication	No. of patients (%) (n=65)	CRSf-low (n=17)	CRSf-high (n=48)	p-value
Pneumonia	30 (6.8)	7	23	< 0.001
Prolonged air leak	4 (0.9)	0	4	0.013
Interstitial pneumonia	2 (0.5)	0	2	0.079
Bronchopleural fistula	3 (0.7)	2	1	0.829
Bronchial asthma	2 (0.5)	1	1	0.759
ARDS	1 (0.2)	0	1	0.215
Atrial fibrillation	21 (4.7)	6	15	0.002
Others	2 (0.5)	1	1	0.759

ARDS, acute respiratory distress syndrome; CRSf, comprehensive risk score fixed.

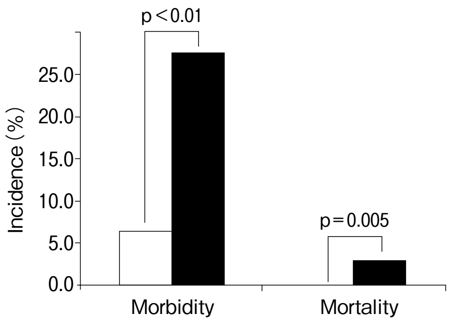

Fig.1. The postoperative morbidity and mortality were significantly higher in the CRSf-high group (closed bar) than CRSf-low group (open bar) ($p < 0.001$, $p = 0.005$, respectively)

III. Results

To estimate the usefulness of the CRSf, we used a ROC curve analysis to determine the cutoff value. At this threshold of PCCs, the Az value was 0.69945 and the cutoff value was 0.112384. We defined levels of CRSf over the cutoff value as being "higher" and levels under the cutoff value as being "lower". Eligible patients were divided into two groups: the CRSf-high (n =175) and -low (n = 269) groups. The clinical characteristics of the patients are summarized in Table 2. Significant differences

Table 4. Logistic regression analysis of predictor for postoperative complications

Variable	Postoperative complication		
	OR	95% CI	p-value
Age (70 years ≦)	1.05	0.55-2.01	0.877
Gender (Male)	4.02	1.38-11.69	0.011
Height (155 cm<)	1.60	0.62-4.10	0.330
Brinkman index (600 ≦)	1.11	0.55-2.23	0.777
Predicted postoperative value			
Pred-VC (<2.5 L)	1.86	0.81-4.26	0.142
Pred-FEV_1 (<1.8 L)	1.00	0.44-2.27	0.998
Pred-%D_{LCO} (≦ 65%)	1.53	0.72-3.23	0.268
CRSf (cut off<)	3.92	2.02-7.59	< 0.001

CI, confidence intervals; CRSf, comprehensive risk score fixed; %D_{LCO}, percentage of predicted diffusing capacity of the lung for carbon monoxide; OR,odds ratio predictors; FEV_1, predicted postoperative forced expiratory volume in 1 second; VC, predicted postoperative vital capacity.

in several variables were observed between the two groups, including age, gender, Brinkman Index, medical history (hypertension, diabetes mellitus, chronic obstructive pulmonary disease, interstitial pneumonia, and ischemic heart disease), and American Society of Anesthesiologists grade.

Fig.1 shows postoperative morbidity and in-hospital mortality of CRSf-high (closed bar) and -low (open bar) groups. They were significantly higher in the CRSf-high group (each $p < 0.001$, $p=0.005$). The details of postoperative complications are shown in Table 3. Postoperative complication occurred in 65 patients (14.6%). The rate of postoperative pneumonia was 6.8%, of prolonged air leakage was 0.9%, and of atrial fibrillation was 4.7%, and all were significantly higher in the CRSf-high group.

To estimate the predictors of postoperative complications, logistic regression analysis was performed (Table 4). The mE-PASS CRSf score was an independent predictor of PCCs after c-VATS (OR: 3.92, $p < 0.001$, respectively).

Ⅳ. Discussion

In this retrospective validation study, we evaluated the preoperative risk assessment in patients with NSCLC who underwent pulmonary lobectomy by c-VATS. These results indicate that, using a cutoff value for the CRSf, mE-PASS can preoperatively predict the risk for postoperative complications. To our knowledge, this is the first report of a postoperative complications prediction score for c-VATS pulmonary lobectomy for primary lung cancer.

Although VATS is performed widely for NSCLC [11)], its preoperative risk score evaluation has not been established. The E-PASS scoring system is simple and easily calculated, and includes only 10 parameters, which are routinely evaluated before surgery. The E-PASS scoring system is useful for predicting postoperative risk not only in gastroenterological surgery [22)], but also in other fields, such as thoracic and vascular surgery [6-8)]. However, since the E-PASS scoring system includes intraoperative factors such as blood loss, operation time, and extent of skin incision, it is difficult to assess the postoperative risk prior to surgery. The mE-PASS scoring system can resolve this problem. The advantage of the mE-PASS scoring system is that it can predict the occurrence of postoperative complications before surgery. Furthermore, mE-PASS reduces the number of variables from 10 to 7, making it simpler than E-PASS. In this study, the SSSf used in the mE-PASS calculation, and which is specific for c-VATS pulmonary lobectomy was determined using the median SSS of 444 patients with E-PASS scores [10)]. The present study demonstrated that the mE-PASS CRSf was useful in predicting the occurrence of PCCs in patients undergoing c-VATS. Using mE-PASS, surgeons can preoperatively determine the risk of surgery.

Previous reports have found that VATS accounts for approximately 70% of all lung cancer surgeries in Japan [23)]. VATS is thought to be minimally invasive, since the SSS of E-PASS is low [7)]. In this study, we instead used the SSSf, which is the median of the SSS, and it was also very low. Despite the low range for the SSSf, in this study it was possible to demonstrate a significant difference in the rate of postoperative pulmonary complications by mE-PASS. Since it is possible to make a perioperative treatment strategy for each patient, mE-PASS was considered to be a useful prediction score for postoperative complications.

It is important to determine the risk factors for PPCs because PPCs cause more than half of all deaths that occur after pulmonary surgery [23]. Postoperative atelectasis often occurs after thoracic surgery, as deep breathing or coughing are restricted due to transection of accessory respiratory muscles, such as the intercostal muscles. The recovery rate of VATS is superior to that of open thoracotomy in the early period, especially in the first 7 days after surgery [24, 25]. Postoperative pulmonary function takes almost 3 months to recover after open thoracotomy. Furthermore, the operation wound of VATS is small, reducing wound pain and making it easier to exhaust sputum, contributing to the prevention of pneumonia and atelectasis [26]. If postoperative risks can be predicted, various perioperative treatment strategies can be tailored for each patient, e.g., use of a breathing exercise training device pre- and postoperatively, application of high-flow nasal cannula immediately after surgery, and cautious postoperative pain management, mobilization, and postoperative rehabilitation from the first postoperative day. These interventions may lead to improvement of surgical outcome of c-VATS.

In this study, the rate of postoperative atrial fibrillation was 4.7%. In general, the onset of atrial fibrillation is often reported as 6.4-16% in the early period after pulmonary lobectomy. However, the results of this study showed the incidence of atrial fibrillation was lower than that in previous reports [27, 28]. The approach in many reports on postoperative complications for pulmonary lobectomy was thoracotomy, since it may be possible that the early period of postoperative pain was affected. Although it is unknown whether atrial fibrillation will be reduced only with this approach (thoracotomy vs. c-VATS), while the resected volume remains the same, a new clinical trial is considered to be necessary to verify this question.

There are several limitations in this study. First of all, the number of cases is small, and it is a retrospective validation study in a single institution. Further investigation by multicenter and prospective validation study will be needed to confirm the utility of mE-PASS more accurately, because the SSSf is the median of the SSS and a large number of cases is necessary to obtain a more accurate SSSf. Currently, we are also undergoing a multicentric prospective validation study, and will report on it after data on sufficient case are collected. Therefore, this retrospective validation study can be one of the useful information.

In summary, the present study demonstrated that the mE-PASS CRSf was useful in predicting the occurrence of PCCs in patients undergoing c-VATS. To our knowledge, this is the first study of mE-PASS in c-VATS pulmonary lobectomy. Appropriate application of this system enables accurate assessment of surgical risk and provides useful information for explaining the possibility of postoperative complications to patients when obtaining informed consent.

Conflict of interest: The authors have no conflict of interest to declare.

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肺癌患者における術後合併症予測スコアの有用性の検討

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要旨

肺癌根治術においては開胸手術よりも低侵襲な video-assisted thoracic surgery (VATS) が普及しているものの，VATS における術後合併症発生予測スコアは明確ではない．本研究では術後合併症発生予測スコアの一つとして提唱されている modified estimation of physiological ability and surgical stress (m-PASS) の有用性を検討する．原発性肺癌に対して VATS で肺癌根治術を行った 444 例を，CRSf- 高値群 (n = 175) と CRSf- 低値群 (n = 269) の 2 群に分類し比較検討した結果，CRSf- 高値群で呼吸器循環器合併症 (PCCs) の発生が有意に多かった．多変量解析では CRSf が，PCCs の独立した予測因子であった (OR: 3.92，$p < 0.001$). mE-PASS は PCCs 発生予測に有用である．