Model of lung cancer surgery risk derived from a Japanese nationwide web-based database of 78 594 patients during 2014 2015

Model of lung cancer surgery risk derived from a Japanese nationwide web-based database of 78 594 patients during 2014–2015[†]

Shunsuke Endo[a,*], Norihiko Ikeda[b], Takashi Kondo[c], Jun Nakajima[d], Haruhiko Kondo[e], Kohei Yokoi[f], Masayuki Chida[g], Masami Sato[h], Shinichi Toyooka[i], Koichi Yoshida[b], Yoshinori Okada[j], Yukio Sato[k], Morihito Okada[l], Meinoshin Okumura[m], Koji Chihara[n], Eriko Fukuchi[o] and Hiroaki Miyata[o]

[a] Department of Thoracic Surgery, Jichi Medical University, Tochigi, Japan
[b] Department of Thoracic Surgery, Tokyo Medical University Hospital, Tokyo, Japan
[c] Department of Thoracic Surgery, Tohoku Medical and Pharmaceutical University Hospital, Miyagi, Japan
[d] Department of Thoracic Surgery, University of Tokyo Graduate School of Medicine, Tokyo, Japan
[e] Department of General Thoracic Surgery, Kyorin University Hospital, Tokyo, Japan
[f] Department of Thoracic Surgery, Nagoya University Graduate School of Medicine, Aichi, Japan
[g] Department of General Thoracic Surgery, Dokkyo Medical University, Tochigi, Japan
[h] Department of General Thoracic Surgery, Graduate School of Medical and Dental Sciences, Kagoshima University, Kagoshima, Japan
[i] Department of Thoracic Surgery, Graduate School of Medicine, Dentistry and Pharmaceutical Sciences, Okayama University, Okayama, Japan
[j] Department of Thoracic Surgery, Institute of Development, Aging and Cancer, Tohoku University, Miyagi, Japan
[k] Faculty of Medicine, Department of Thoracic Surgery, University of Tsukuba, Ibaraki, Japan
[l] Department of Surgical Oncology, Hiroshima University, Hiroshima, Japan
[m] Department of General Thoracic Surgery, Osaka University Graduate School of Medicine, Osaka, Japan
[n] Division of Thoracic Surgery, Shizuoka Hospital, Shizuoka, Japan
[o] Department of Healthcare Quality Assessment, University of Tokyo Graduate School of Medicine, Tokyo, Japan

* Corresponding author. Department of Thoracic Surgery, Jichi Medical University, Tochigi 329-0498, Japan. Tel: +81-28-5587368; fax: +81-28-5446271;
  e-mail: tcvshun@jichi.ac.jp (S. Endo).

Abstract

OBJECTIVES: Using data obtained from a Japanese nationwide annual database with web-based data entry, we developed a risk model of mortality and morbidity after lung cancer surgery.

METHODS: The characteristics and operative and postoperative data from 80 095 patients who underwent lung cancer surgery were entered into the annual National Clinical Database of Japan data sets for 2014 and 2015. After excluding 1501 patients, the development data set for risk models included 38 277 patients entering in 2014 and the validation data set included 40 317 patients entering in 2015. Receiver–operating characteristic curves were generated for the outcomes of mortality and composite mortality/major morbidity. The concordance index was used to assess the discriminatory ability and validity of the model.

RESULTS: The 30-day mortality and overall mortality rates, including in-hospital deaths, were 0.4% and 0.8%, respectively, in 2014, and 0.4% and 0.8%, respectively, in 2015. The rate of major morbidity was 5.6% in 2014 and 5.6% in 2015. Several risk factors were significantly associated with mortality, namely, male sex, performance status, comorbidities of interstitial pneumonia and liver cirrhosis, haemodialysis and the surgical procedure pneumonectomy. The concordance index for mortality and composite mortality/major morbidity was 0.854 ($P < 0.001$) and 0.718 ($P < 0.001$), respectively, for the development data set and 0.849 ($P < 0.001$) and 0.723 ($P < 0.001$), respectively, for the validation data set.

CONCLUSIONS: This model was satisfactory for predicting surgical outcomes after pulmonary resection for lung cancer in Japan and will aid preoperative assessment and improve clinical outcomes for lung cancer surgery.

Keywords: Risk model • Surgery • Lung cancer • Nationwide survey

INTRODUCTION

Lung cancer is a leading cause of death worldwide. Surgery remains a mainstay for complete cure. Because of the large number of elderly people in Japan, lung cancer patients frequently have multiple comorbidities, which increase mortality and morbidity risks. Risk-adjusted outcome analysis is demanding when used to assess preoperative risk, monitor surgical performance and implement measures that improve care.

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Table 1: Baseline characteristics

	Risk model set (2014)		Validation set (2015)	
	n	%	*n*	%
Total	38 277	100	40 317	100
Age (years) ± SD	69.35 ± 9.31		69.6 ± 9.24	
Male	23 639	61.8	24 819	61.6
BMI ± SD	22.7 ± 3.36		22.7 ± 3.37	
Cigarette smoking	24 573	64.2	26 214	65.0
<10 pack-years	1841	4.8	2020	5.0
10–30 pack-years	4515	11.8	4877	12.1
30 pack-years or more	18 217	47.6	19 317	47.9
Cigarette smoking history				
Past (stopped more than 30 days before)	20 171	52.7	22 050	54.7
Current	4402	11.5	4164	10.3
Never	13 704	35.8	14 103	35.0
PS				
PS0	31 462	82.2	33 775	83.8
PS1	5285	13.8	5051	12.5
PS2	1240	3.2	1206	3.0
PS3	225	0.6	194	0.5
PS4	12	0.0	11	0.0
Not available	53	0.1	80	0.2
Comorbidities				
Diabetes mellitus	5553	14.5	6111	15.2
Coronary artery disease	2037	5.3	2326	5.8
Haemodialysis	275	0.7	287	0.7
Liver cirrhosis (Child–Pugh Class B/C)	211	0.6	158	0.4
Interstitial pneumonia	1783	4.7	1836	4.6
Central nerve system disorder	2254	5.9	2461	6.1
Spirogram				
%VC <80%	4261	11.1	4442	11.0
%FEV_1 <70%	4787	12.5	5056	12.5
%FEV_1 <70%	11 354	29.7	12 094	30.0
%FEV_1 <50%	1090	2.8	1136	2.8
Induction treatment				
Induction chemoradiotherapy	474	1.2	495	1.2
Induction chemotherapy	509	1.3	455	1.1
Induction radiotherapy	45	0.1	49	0.1
Clinical stage				
IA	23 194	60.6	24 810.0	61.5
IB	7220	18.9	7640.0	18.9
IIA	2990	7.8	2984.0	7.4
IIB	1743	4.6	1742.0	4.3
IIIA	2447	6.4	2423.0	6.0
IIIB and IV	584	1.5	555.0	1.4
Approach				
Mini-thoracotomy <8 cm	9806	25.6	9778	24.3
Complete VATS	15 078	39.4	16 848	41.8
Thoracotomy	13 393	35.0	13 691	34.0
Primary procedure				
Wedge resection	5568	14.5	5930	14.7
Segmentectomy	4192	11.0	4253	10.5
Lobectomy	27 962	73.1	29 570	73.3
Sleeve lobectomy	491	1.3	548	1.4
Pneumonectomy	508	1.3	520	1.3
Nodal dissection				
Not performed	6584	17.2	6951	17.2
Hilar dissection	5568	14.5	6012	14.9
Lobe-specific mediastinal dissection	15 539	40.6	17 410	43.2
Systematic mediastinal dissection	10 586	27.6	9944	24.7
Resectability				
Complete resection	36 217	94.6	38 352	95.1
Incomplete resection	1557	4.1	1509	3.7
Unclassified	503	1.3	456	1.1
Hospital stratified by annual volume				
Low: <50 operations (506 SUs in 2014 and 510 SUs in 2015)	9771	25.4	9768	24.2
Middle: 50–100 operations (195 SUs either in 2014 or in 2015)	13 584	35.5	13 785	34.2
High: >100 operations (96 SUs in 2014 and 109 SUs in 2015)	14 922	39.0	16 764	41.6

BMI: body mass index; VATS: video-assisted thoracic surgery; SUs: surgical units; SD: standard deviation; PS: performance status; FVC_1: forced vital capacity in 1 s; VC: vital capacity. Clinical stage: 7th edition TNM classification by UICC.

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Table 2: Frequency of major complications (rate)

Variable	Values	
	Risk model set (2014) (*n* = 38 277)	Validation set (2015) (*n* = 40 317)
Total	2134 (5.6%)	2261 (5.6%)
Respiratory failure	220 (0.6%)	200 (0.5%)
Bronchopleural fistula	130 (0.3%)	129 (0.3%)
Pulmonary embolus	41 (0.1%)	32 (0.1%)
Pneumonia	713 (1.9%)	771 (1.9%)
Unexpected return to operating room	83 (0.2%)	59 (0.1%)
Myocardial infarction	21 (0.1%)	17 (0.0%)
Atrial arrhythmia	627 (1.6%)	727 (1.8%)
Renal failure	33 (0.1%)	26 (0.1%)
Chylothorax	271 (0.7%)	271 (0.7%)
Postoperative blood transfusion	148 (0.4%)	143 (0.4%)

Respiratory failure includes patients who required tracheal intubation, tracheostomy or initial ventilatory support for longer than 48 h. Renal failure includes patients who required haemodialysis postoperatively or a postoperative increase in serum creatinine concentration to greater than 4 mg/dl or 3 times the preoperative value.

Table 3: Mortality and major morbidity (rate)

	Risk model set (2014) (*n* = 38 277)	Validation set (2015) (*n* = 40317)
Death within 30 days or in hospital	315 (0.8%)	309 (0.8%)
In-hospital death	257 (0.7%)	264 (0.7%)
In-hospital death within 30 days	96 (0.3%)	123 (0.3%)
In-hospital death after 30 days	161 (0.4%)	141 (0.3%)
Death within 30 days	154 (0.4%)	168 (0.4%)
Major morbidity	2134 (5.6%)	2261 (5.6%)
Death within 30 days or in hospital, or major morbidity	2241 (5.9%)	2349 (5.9%)

In-hospital deaths include deaths during the index hospitalization even if the patient died after transfer to another hospital.

In 2011, the National Clinical Database (NCD) of Japan adopted an annual web-based data collection system. The NCD is a nationwide system that links data collection to the first level of surgical specialization in the Japanese Surgical Board Certification System. In 2014, data on 1.6 million surgical procedures from more than 4000 hospitals were collected [1]. On the basis of the existing NCD system, an NCD specializing in general thoracic surgery was launched in 2014. The data registration system and information recorded are described in detail in our previous report [2]. The NCD for general thoracic surgery is part of the second level of specialization in general thoracic surgery and the accreditation system for educational institutions. In total, 80 095 lung cancer operations were registered in the 2014 and 2015 data sets. More than 95% of all pulmonary resections for lung cancer registered with the Regional Bureau of Health and Welfare in Japan were accounted for in the NCD [3].

In this study, we used the NCD for general thoracic surgery to develop and validate a model estimating individualized risk for patients undergoing pulmonary resection for lung cancer.

MATERIALS AND METHODS

Patient population

The study population for the current analysis was derived from 2 annual data sets (2014 and 2015) that included information on persons who underwent surgical resection for primary lung cancer (at 797 surgical units in 2014 and 814 surgical units in 2015). Surgical approach was categorized as thoracotomy or as a minimally invasive approach, including complete video-assisted thoracoscopic surgery and mini-thoracotomy with a wound length of 8 cm or less. The variable 'surgical approach' was excluded in the development of risk models, because decisions regarding surgical approach were biased by variability in patient selection at the different centres. The surgical procedures included wedge resection, segmentectomy, lobectomy, sleeve lobectomy, bilobectomy and pneumonectomy. Sleeve lobectomy or bilobectomy was entered as a simple variable (lobectomy or bilobectomy) in the analysis, because decisions regarding selection of sleeve lobectomy varied among centres and because few patients underwent bilobectomy (*n* = 143 in 2014 and *n* = 134 in 2015). Nodal dissection was categorized as hilar, lobe-specific mediastinal or systematic, as shown in Table 1.

Patients were excluded if they had undergone procedures with no curative intent (*n* = 363 in 2014 and *n* = 359 in 2015), extrapleural pneumonectomy, completion pneumonectomy, emergency surgery or combined procedures for both lungs or if they had been transported by ambulance. Of the 39 029 patients in 2014 and 41 016 patients in 2015 who were eligible for analysis, 1501 (*n* = 752 in 2014 and *n* = 749 in 2015) were excluded from the analysis. The development data set for risk models included 38 277 patients entering in 2014, and the validation data set included 40 317 patients entering in 2015.

Outcome measures

The primary outcome measures were operative mortality and the composite outcome of mortality/major morbidity. Operative mortality included patients who died within 30 days after surgery, regardless of hospitalization status, and those who died within the index hospitalization, even if death occurred after transfer to another hospital.

Major morbidity was defined in accordance with the Society of Thoracic Surgeons (STS) risk models as shown in Table 2 [4, 5].

Statistical analysis

For the multivariate logistic regression analysis, a risk model set, registered in 2014 (*n* = 38 277), and a validation set, registered in 2015 (*n* = 40 317), were created to estimate associations of patient

Table 4:　Mortality and major morbidity (rate), stratified by surgical procedure, resectability and hospital annual volume

	Mortality		Mortality and major morbidity	
	Risk model set (2014)	Validation set (2015)	Risk model set (2014)	Validation set (2015)
Primary procedure				
Wedge resection	27 (0.5%)	27 (0.5%)	138 (2.5%)	143 (2.4%)
Segmentectomy	17 (0.4%)	18 (0.8%)	168 (4.0%)	179 (4.2%)
Lobectomy	249 (0.9%)	243 (0.8%)	1837 (6.6%)	1931 (6.5%)
Pneumonectomy	20 (3.9%)	16 (3.1%)	90 (17.1%)	84 (16.2%)
Resectability				
Complete resection	280 (0.8%)	280 (0.7%)	2017 (5.6%)	2149 (5.6%)
Incomplete resection	28 (1.8%)	22 (1.5%)	75 (4.8%)	85 (5.6%)
Unclassified	7 (1.4%)	7 (1.5%)	32 (6.4%)	27 (5.9%)
Hospital stratified by annual volume				
Low: <50 operations	90 (0.9%)	86 (0.9%)	522 (5.3%)	525 (5.4%)
Middle: 50–100 operations	124 (0.9%)	106 (0.9%)	756 (5.6%)	739 (5.4%)
High: >100 operations	101 (0.7%)	117 (0.7%)	963 (6.5%)	1085 (6.5%)

baseline characteristics with the primary outcome measures of operative mortality and composite mortality/major morbidity. The variables entered in the model were selected with the χ^2 test, for categorical covariates, and the unpaired *t*-test, for continuous covariates. All variables that were significant at $P < 0.05$ and were present in at least 0.5% of the sample were included in the multivariate stepwise logistic regression analysis of both outcomes. Missing or inconsistent values for age or spirography were substituted with the most frequent categories. Model discrimination was assessed by examining the area under the receiver–operating characteristics curve (C-statistic). Model variation was analysed using the annual data registered in 2015. Analyses were performed with the IBM SPSS Statistics software package (version 23; IBM Corp., Armonk, NY, USA).

RESULTS

Risk profile of study population

The number of patients who underwent lung cancer surgery was 38 277 in the risk model set (1 January 2014 through 31 December 2014) and 40 317 in the validation set (1 January 2015 through 31 December 2015). The baseline characteristics of these patient groups were similar (Table 1).

Outcomes

The most frequent cause of major morbidity was respiratory failure after pneumonia and atrial arrhythmia (Table 2). In the risk model set, there were 315 (0.8%) operative deaths, and major morbidity was noted in 2134 patients (5.6%). In the validation set, there were 309 (0.8%) operative deaths, and major morbidity was noted in 2261 patients (5.6%) (Table 3). Mortality and major morbidity rates were high in patients who underwent pneumonectomy and not influenced by hospital volume (Table 4). More than half of the dead patients died from respiratory-related death, including acute exacerbation of interstitial pneumonia, pneumonia and other respiratory failure. The outcomes of the 2 data sets were almost identical.

Model result

Multivariate risk models were developed, and the final logistic model, with odd ratios and 95% confidence intervals (CIs), is presented in Table 5, which shows the associations of patient baseline characteristics with the outcome measures of mortality and mortality/major morbidity. Nineteen variables were associated with mortality, and 25 variables were associated with mortality/ morbidity.

To evaluate model performance, we used the concordance C-index (a measure of model discrimination), which is the area under the receiver–operating characteristics curve. The C-indices were 0.854 (95% CI, 0.835–0.874; $P < 0.001$) for mortality and 0.718 (95% CI, 0.708–0.729; $P < 0.001$) for mortality/major morbidity. The C-indices in the validation data sets for these 2 models were 0.849 (95% CI, 0.830–0.868; $P < 0.001$) and 0.723 (95% CI, 0.713–0.733; $P < 0.001$), respectively.

DISCUSSION

Surgery is a promising treatment for patients with early stage lung cancer, even though some postoperative complications are unavoidable. Risk ratios for postoperative complications are affected by patient demographics, oncologic factors such as histology and staging, type of surgical procedure and surgeon performance. The STS [5], the US National Cancer Database [6], the European Society of Thoracic Surgeons (ESTS) [7] and institutions in other countries [8] have developed risk models for lung cancer surgery, to assess quality measures for surgeon performance and preoperative decision-making.

Obstacles to establishing optimal risk models

Several limitations in establishing ideal risk models have been described [9], as follows:

(i) Risk models should be based on a large database covering as many operations as possible. The criteria used to select patients for surgery may vary by centre, which would have affected the model. A clinical database will not yield an accurate risk model

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Table 5: Predictors of mortality and composite mortality/major morbidity

	P-value	OR (95% CI)
Mortality model		
Male	<0.001	2.366 (1.533–3.651)
Five-year increase in age (60–79 years)	<0.001	1.420 (1.299–1.551)
PS		
PS1	0.006	1.457 (1.113–1.908)
PS2 or higher	<0.001	2.644 (1.836–3.806)
%VC 10% decrease (from 100% to 50%)	<0.001	1.380 (1.277–1.491)
Liver cirrhosis (Child–Pugh Class B/C)	0.009	3.075 (1.320–7.161)
Haemodialysis	0.006	2.883 (1.357–6.125)
Interstitial pneumonia	<0.001	3.690 (2.790–4.880)
Ischaemic heart disease (with/without intervention)	0.023	1.504 (1.057–2.140)
Smoking history	0.019	1.711 (1.093–2.677)
Tumour size >3 cm (radiological)	0.027	1.354 (1.036–1.771)
Clinical stage		
II or higher	0.006	1.537 (1.130–2.091)
III or higher	0.009	1.568 (1.120–2.196)
Superior sulcus tumour	0.032	1.752 (1.048–2.931)
Surgical procedure		
Right lower lobectomy	0.001	1.604 (1.213–2.122)
Lobectomy or bilobectomy	<0.001	1.973 (1.382–2.816)
Pneumonectomy	<0.001	5.224 (2.865–9.523)
Chest wall resection (other than first rib)	<0.001	2.820 (1.584–5.019)
Histology other than adenocarcinoma	0.001	1.502 (1.181–1.911)
Mortality and morbidity model		
Male	<0.001	1.724 (1.519–1.917)
Five-year increase in age (60–79 years)	<0.001	1.160 (1.124–1.197)
Cigarette smoking 30 pack-years or more	<0.001	1.236 (1.105–1.382)
PS		
PS1	0.001	1.228 (1.094–1.379)
PS2 or higher	<0.001	1.473 (1.216–1.784)
%VC 10% decrease (from 100% to 50%)	<0.001	1.148 (1.108–1.188)
%FEV$_1$ <70%	0.002	1.164 (1.055–1.284)
%FEV$_1$ <50%	<0.001	1.506 (1.213–1.870)
Haemodialysis	0.003	1.847 (1.226–2.781)
Interstitial pneumonia	<0.001	2.293 (1.978–2.658)
Stroke	0.040	1.182 (1.007–1.387)
Untreated diabetes mellitus	0.021	1.567 (1.069–2.299)
Autoimmune disease	0.016	1.405 (1.065–1.854)
Arrhythmia	<0.001	1.849 (1.554–2.201)
Induction radiotherapy or chemoradiotherapy	<0.001	1.762 (1.347–2.304)
Clinical Stage II or higher	<0.001	1.341 (1.209–1.487)
Surgical procedure		
Pneumonectomy	<0.001	3.092 (2.296–4.165)
Lobectomy or bilobectomy	<0.001	1.475 (1.248–1.743)
Nodal dissection		
Hilar or lobe specific or systematic	<0.001	1.999 (1.621–2.465)
Systematic	<0.001	1.210 (1.096–1.335)
Combined resection		
Pulmonary artery	0.019	1.721 (1.095–2.706)
Chest wall (other than first rib)	0.005	1.592 (1.152–2.199)
Chest wall (first rib)	0.004	2.584 (1.356–4.925)
Wedge resection or segmentectomy of lung	<0.001	1.558 (1.222–1.986)
Histology other than adenocarcinoma	<0.001	1.229 (1.115–1.354)

VC: vital capacity; FEV$_1$: forced expiratory volume in 1 s; CI: confidence interval; PS: performance status; OR: odds ratio. Clinical stage: 7th edition TNM classification by UICC.

unless there is a high participation rate in data entry [2]. Different investigators evaluating the same predictors by means of regression analysis might obtain heterogeneous results because of sample biases at the time of the traditional training-and-test method for model building. To maintain statistical reliability and reproducibility, bootstrap analysis is recommended [9]. In addition, the use of different samples is recommended for model validation processes. Data registered in the following year, 2015, were used for validation, to show the reproducibility and reliability of our risk model.

(ii) The use of morbidity as an outcome is problematic. Although it is defined in the manual for the case report form in the NCD registration system [2], morbidity is subject to entry error or under-reporting. In Japan, data managers receive instruction on the correct registration of postoperative complications, at the NCD seminar at the annual meeting of the Japanese Association for Chest Surgery.

(iii) Important variables, such as a body mass index >35, are not included in the present model because they are infrequent in

Table 6: Comparison of risk models for pulmonary resection in selected large clinical databases

	National Clinical Database Japan	Society of Thoracic Surgeons (USA)	European Society of Thoracic Surgeons
Data entry	78 594	27 844	47 960
No. of surgical units	799	231	>200
Survey (year)	2014–2015	2012–2014	2007–2015
Patients	Primary lung cancer	Primary lung cancer	Anatomical lung resection
Age (years) ± SD	69.4 ± 9.3	67.2 ± 10.1	62.6 ± 11.4
Male	61.70%	45.40%	68.00%
BMI ± SD	22.7 ± 3.4	27.6 ± 6.2	25.5 ± 4.5
Coronary artery disease	5.50%	22.30%	7.70%
Renal failure	0.7% (haemodialysis)	1.80%	8.30%
Diabetes mellitus	14.80%	18.50%	2.80%
Induction treatment	2.50%	6.50%	9.90%
Thoracotomy	34.50%	38.40%	86.90%
Pneumonectomy	1.30%	4.00%	10.50%
Operative mortality	0.8% (30 days + in-hospital)	1.4% (30 days)	2.7% (30 days)
Major morbidity	5.60%	9.10%	18.40%

BMI: body mass index.

the population [10]. The NCD does not include race or presence of peripheral vascular disease among the preoperative variables. In addition, deep vein thrombosis and sepsis are not included among postoperative complications. However, these complications are rare in Japan. The STS and ESTS databases do not include interstitial pneumonia or liver cirrhosis as variables [5, 7], even though our model identified them as significant risk factors for lung cancer surgery. These variations in risk models, which are related to regional differences in data collection, should be carefully reviewed. A worldwide clinical database, with the same variables included in all countries, is desirable [11].

(iv) Previously reported risk models by the STS and ESTS defined operative mortality as death during the index hospitalization for surgery or within 30 days of the procedure. In our database, operative mortality classified death after transfer to another hospital over 30 days after surgery as an in-hospital death. The universal health care system in Japan allows patients with serious comorbidities or postoperative complications to be transferred to another hospital. Mortality at 90 days after thoracic surgery is twice that at 30 days [12]. In the present study, the value for 30-day mortality plus in-hospital mortality is double that for 30-day mortality and thus is likely to be approximate 90-day mortality.

(v) Data quality affects risk model analysis. Databases should be audited regularly to maintain the quality of information; however, the audit of even a small fraction of a database requires substantial effort. To reduce the burden of ensuring data quality, a web audit system was developed for the Japan NCD system. Surgeons provide anonymous operative notes of patients randomly selected by the NCD, the number of which is equivalent to approximately 0.5% of registered cases. These notes are submitted to the Japanese Board of General Thoracic Surgery at the time of application for board certification for general thoracic surgery. A committee authorized by the NCD determines inter-rater reliability between these samples and Internet-based data from the NCD. The results indicate that the correctness of data on age, gender, procedure, disease, operative time, blood loss and participating surgeons was greater than 94% [2]. Starting in

2017, the web audit will encompass other variables related to patient demographics and outcomes, which will be evaluated using hospitalization summaries randomly selected by the NCD office.

The aim of this study was to use the comprehensive NCD on general thoracic surgery to develop a risk model for lung cancer patients undergoing pulmonary resection. The 30-day and the rate of the composite outcome morbidity/major morbidity were lower than those for the STS and ESTS databases, perhaps because of differences in clinical characteristics (such as body mass index and comorbidities), clinical staging and type of surgery, i.e. the so-called 'cherry-picking' problem. Patient demographics in the NCD differed greatly from those in the STS and ESTS database-based risk model of 2016, specifically the distributions of patients undergoing induction treatment, thoracotomy and pneumonectomy (Table 6) [5, 7]. Despite differences in operative morbidity and mortality between the STS risk model and our NCD model, there were several shared risk factors for operative mortality and morbidity. If input items were standardized, a large clinical database could overcome problems related to regional disparities.

Older age and being male were predictors in both risk models [5, 6]. Male sex has consistently been identified as a risk factor in other models of lung cancer surgery risk. The fact that advancing age had adverse effects on mortality and morbidity in the present patients younger than 80 years but not in those aged 80 years or older is likely attributable to selection bias. Physical performance might be similar for surgical candidates in these age groups. Interstitial pneumonia and comorbidities such as haemodialysis and liver cirrhosis were significant risk factors. Interstitial pneumonia is diagnosed on the basis of a radiologic finding of a fibrotic shadow with traction bronchiolectasis in bilateral basal segments, regardless of respiratory symptoms and diffusing capacity of the lung carbon monoxide. Affected patients are susceptible to lethal postoperative respiratory failure from acute exacerbation of interstitial pneumonia [13]. The diffusing capacity can be accepted as important predictors of operative mortality and morbidity after lung cancer resection [7]; therefore, these data have been documented since 2017.

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Respiratory acidosis caused by respiratory failure is fatal for patients undergoing maintenance haemodialysis who cannot compensate for respiratory acidosis and hyperkalaemia by metabolic alkalosis [14]. Child–Pugh Class B/C liver cirrhosis can cause malnutrition, prolonged pleural discharge and bleeding and may thus be a risk factor [15].

A tumour diameter >3 cm and a clinical stage of 2 or higher are important variables relating to extensive resection and are likely to be important risk factors. Evidence from numerous studies indicates that minimally invasive surgery, including video-assisted thoracoscopic surgery, has favourable effects on mortality and morbidity. However, candidates for minimally invasive surgery may be more likely to have early lung cancer. Thus, the surgical approach should not be included in the risk calculation because of likely selection bias and institutional bias. Propensity-matched analysis is required in order to clarify risk with respect to the use of a minimally invasive approach [16]. In addition, because of the increasing number of patients with less invasive adenocarcinoma, the variable non-adenocarcinoma was identified as a risk factor.

Pneumonectomy resulting in cardiopulmonary dysfunction and bronchopleural fistula is an important risk factor in lung cancer surgery [17]. In our model, other risk factors were right lower lobectomy—which can result in the presence of a large pleural dead space in the thoracic cavity, where bronchopleural fistulae might develop [18]—and chest wall resections other than resection of the first rib, which may cause postoperative respiratory failure [19].

Our analysis showed that risk models based on the NCD 2014 could be validated with the NCD 2015. Validation analysis confirmed the feasibility of the risk model. However, patient demographics, lung cancer oncology and treatment strategy, among other factors, will continue to change as societies age and medical science advances. Furthermore, the 8th edition of the tumour, node and metastasis classification for lung cancer was published by the International Association for the Study of Lung Cancer. If adverse effects resulting in operative mortality and morbidity are changing, the risk models for lung cancer surgery will need to be reviewed, particularly in rapidly changing societies. Our NCD data collection system will continue to enable data managers to respond to changes in data input, as the system is able to annually update risk models for lung cancer surgery.

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APPENDIX. CONFERENCE DISCUSSION

Dr W. Weder (Zurich, Switzerland): Are you prospectively validating the quality of your risk model, with other words, are you looking what's happening to these patients you have predicted a certain risk during a year?

Dr Endo: We performed just a retrospective analysis, not prospective.

Dr Weder: Yes, I understand, but are you now prospectively evaluating the quality of the risk model?

Dr Endo: I hope so.

Dr Weder: And second question: did you look at the hospital-specific mortality, especially at the risk of, was it dependent on the size? I have not seen it in the data.

Dr Endo: In our data, we cannot find the difference between hospitals depending on volumes of surgery.

Dr K. Naunheim (St Louis, MO, USA): In the USA, we are also struggling with quality improvement and feedback, and it is hard to know what to do with this information. Our own databases, like yours, give the observed to expected ratio and there is a statistical analysis that will tell you, just because you are 1.1 or 1.2 does not mean you are outside the realm of good surgery. Sometimes that could be just a statistical blip. I want to know whether you have some method for statistically analysing the ODE. Do you feed that information back to the surgeon, is that something they get and if they are outside the bounds of acceptable practice, what sort of remediation, what sort of help can you give them to try to bring them back to where they should be, because it is not that they are bad people, they are necessarily bad surgeons. Almost everybody who is a thoracic surgeon can be made better. The whole idea of quality improvement is not punitive, is not to call people names or kick them out of the profession, we need to re-educate them and bring them back in, so I do not know whether you have any programmes to help re-educate surgeons.

Dr Endo: In our field of thoracic surgery, we do not perform such audit systems, to improve the surgical performance. But in the field of cardiovascular surgeries, the teams can advise the improvement of the hospital performance, actually, in the last year. I also hope that if we find some bad hospital performance I can recommend some improvement.

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