

Pulmonary Resection in Patients Aged 80 Years or Over with Clinical Stage I Non-small Cell Lung Cancer

Prognostic Factors for Overall Survival and Risk Factors for Postoperative Complications

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Introduction: This retrospective study was designed to identify the predictors of long-term survival and the risk factors for complications after surgery in patients aged 80 years or older with clinical (c)-stage I non-small cell lung cancer.

Methods: The Japanese Joint Committee of Lung Cancer Registry collated the clinicopathological profiles and outcomes of 13,344 patients who underwent pulmonary resection for primary lung cancer in 1999. The data of 367 patients aged 80 years or older with c-stage I non-small cell lung cancer were analyzed for prognostic factors and risk factors for postoperative complications.

Results: The median age was 82 years (range, 80–90 years). Of the total patient number, 102 (27.8%) had some form of comorbidity diagnosed preoperatively. Thirty-one (8.4%) patients presented with postoperative complications, and the operative mortality was 1.4%. The 5-year survival rates were 55.7% for c-stage I patients, 62.0% for c-stage IA, and 47.2% for c-stage IB. Advanced pathologic stage and comorbidity were significant independent predictors of shortened survival ($p < 0.0001$ and $p = 0.032$, respectively). Comorbidity and mediastinal lymph node dissection were identified as factors that increased the risk of postoperative complications ($p < 0.0001$ and $p = 0.036$, respectively). Survival rates were independent of the extent of pulmonary resection (lobectomy or limited resection).

Conclusions: Octogenarian patients with c-stage I lung cancer in this study had a satisfactory long-term outcome and low-mortality rate. Comorbidity is a factor associated with both prognosis and operative risks. A selection of the patients who would be curable without mediastinal lymph node dissection after an accurate preoperative staging is beneficial to decrease the postoperative complications because this procedure is a risk factor.

Key Words: Clinical stage I lung cancer, Surgery, Octogenarian, Prognostic factor, Risk factor for postoperative complication, Limited resection.

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The average age of the general population is increasing in many countries including Japan.¹ According to the Japanese national statistics on population, the proportion of people older than 80 years will swell from 5.2% in 2006 to 9.6% in 2020.² Lung cancer is the leading cause of cancer-related deaths in many countries, and patients older than 80 years account for 14% of all lung cancers.^{3,4} Thus, the number of elderly lung cancer patients is increasing rapidly worldwide.

The current gold standard treatment of early-stage lung cancer is the resection of the primary tumor plus the lymph nodes, whether they are involved or not.⁵ Pulmonary resection is feasible and safe in octogenarians, given the appropriate selection of surgical candidates,^{6–10} and evidence-based guidelines recommend that lung cancer patients should not be denied resection on the grounds of age alone.¹¹ However, elderly patients who undergo pulmonary resection have a higher incidence of morbidity and mortality than that of younger patients because of the increased incidence of adverse medical conditions and reduced cardiopulmonary function with aging.¹² In addition, the long-term benefit of surgery in elderly patients remains unclear because aging itself is an independent significant predictor of poor survival.^{13,14}

Elderly patients are generally diagnosed with early-stage lung cancer compared with younger patients.¹⁵ Although lobectomy is usually recommended for early lung

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cancer, limited surgery and other less invasive nonsurgical alternatives could be indicated if the patient has an increased risk of complications. Decisions regarding the treatment strategy must, therefore, carefully balance the risks of postsurgical morbidity and mortality with those affecting cancer recurrence and long-term survival.

The Japanese Joint Committee of Lung Cancer Registry conducted retrospective studies on cancer patients in 1989, 1994, and 1999 after a 5-year follow-up.^{16,17} National data were collected for 13,010 lung cancers that were resected surgically in 1999. This study focused on patients aged 80 years and older with clinical (c)-stage I lung cancer to elucidate predictors of long-term survival and risk factors for postoperative complications.

PATIENTS AND METHODS

Registry

The Japanese Joint Committee of Lung Cancer Registry performed a nationwide retrospective registry study on prognosis and clinicopathological profiles of patients with primary lung cancer surgically treated in 1999 in Japan. The committee received the registries of 13,334 patients from 387 teaching hospitals across Japan. The questionnaire comprised 32 items including gender, age, c-T, c-N, c-M, c-stage, preoperative treatment, surgical procedure (pneumonectomy, lobectomy, segmentectomy, or wedge resection), extent of lymph node dissection (ND0-1 or ND2: ND0, without lymph node dissection or lymph node sampling; ND1, intrapulmonary and hilar lymph node dissection; ND2, ND1 plus mediastinal lymph node dissection), curability, residual tumor, diameter of surgical tumor specimen, histology, pathologic (p)-stage, comorbidity, preoperative Eastern Cooperative Oncology Group performance status, postoperative complications, survival time, and cause of death. For the tumor, node, metastasis staging, chest radiograph, computed tomography (CT) of the chest, CT or ultrasound of the upper abdomen, whole-brain CT or magnetic resonance imaging, and bone scintigraphy were performed.

Patients

The study focused on patients with c-stage-I non-small cell lung cancer (NSCLC) in octogenarians. Of the 13,334 registered patients, 602 (4.5%) were aged 80 years or older. Clinical-stage-I patients accounted for 77.6% (467 patients) of this age group, nine patients (1.5%) with c-stage IIA, 55 (9.1%) with IIB, 46 (7.6%) with IIIA, 12 (2.0%) with IIIB, and six (1.0%) with c-stage IV (c-stage was not described in seven patients). One hundred patients were excluded because of previous treatment for lung cancer, incomplete resection, small cell carcinoma histology, low-grade malignant histology, or insufficient information on the factors of interest. The remaining 367 patients were enrolled in the study and followed for at least 5 years after surgery.

Comorbidities and Postoperative Complications

Comorbidities and postoperative complications were diagnosed and recorded during daily clinical practice by laboratory, radiologic, and physiological examinations. The

questionnaires regarding comorbidity comprised 11 items: active smoking history within 1 month before surgery, obesity (body mass index, ≥ 30 kg/m²), cerebrovascular or neurologic diseases, chronic obstructive pulmonary disease (forced expiratory volume in 1 second $\leq 40\%$), interstitial pneumonitis (apparent interstitial shadow detected by chest CT), ischemic heart disease (positive stress test), renal dysfunction (serum creatinine ≥ 2.0 mg/dl), liver cirrhosis (Child-Turcotte class B or worse), diabetes mellitus (HbA1C $\geq 8.0\%$), anemia (Hb ≤ 8.0 g/dl), and autoimmune disease. The postoperative complications were as follows: wound infection (accompanying wound failure), postoperative hemorrhage (500 mL/h or more), prolonged air leakage (2 weeks or longer), chylothorax (1500 mL/d or more), bronchopleural fistula, bronchovascular fistula, pulmonary embolism, empyema, pneumonia (presenting abnormal shadow by chest radiograph), respiratory failure (needed mechanical ventilation for 3 days or longer), myocardial infarction, and cerebral infarction.

Statistical Analysis

The survival time was measured from the date of surgery to the date of the most recent follow-up examination. Survival was calculated by the Kaplan-Meier method, and differences in survival were assessed by log-rank analysis. A multivariate analysis for prognostic factors was performed using the Cox proportional hazard regression model. A logistic regression model of the multivariate analysis results was used to identify the risk factors for postoperative complications. The *p* values less than 0.05 were considered statistically significant. Data are presented as mean \pm standard deviation. Operative mortality included all patients who died within the first 30 days after surgery or during the same hospitalization.

RESULTS

Patient Characteristics

Table 1 summarizes the patient characteristics. The mean age was 82.3 years (median, 82 years; range, 80–90 years). The tumor histology was as follows: adenocarcinoma in 245 patients (66.8%), squamous cell carcinoma in 100 (27.2%), large cell carcinoma in 14 (3.8%), adenosquamous carcinoma in seven (1.9%), and one pleomorphic or sarcomatoid carcinoma. A total of 245 lobectomies and 122 limited resections were performed. Limited resections included 80 wedge resections and 42 segmentectomies. Concerning the c-T stage, limited resections were performed in 94 (43.9%) of 214 patients with cT1 diseases and 28 (18.3%) of 153 patients with cT2 disease. Pneumonectomies were not performed in this cohort. A systematic mediastinal lymph node dissection (ND2) was performed in 127 patients only. According to the c-T stage, ND2 was performed in 69 (32.2%) of the 214 patients with cT1 diseases and 58 (37.9%) of the 153 patients with cT2 disease. After pathologic diagnosis of the surgical specimens, 300 patients remained as stage I, whereas 67 patients were diagnosed with a more advanced disease including 44 stage II patients and 23 stage III patients. There were 53 pathologic node-positive patients (14.4%). The mean tumor diameter was 30.6 ± 14.9 mm, with 113 tumors (30.8%) smaller than 20 mm and 21 tumors (5.7%) larger than

TABLE 1. Characteristics and Overall 5-yr Survival Rates According to Potential Prognostic Factors of Clinical Stage I Patients (n = 367)

Variable	n	%	5-yr Survival Rate (%)	p
Age, median (range)	82 (80–90)		56.1	
Gender				
Male	232	63.2	47.9	0.0006
Female	135	36.8	68.8	
Performance status				
0 or 1	346	94.3	56.3	0.0563
2 or 3	21	5.7	37.1	
Smoking status				
Current smoker	40	10.9	30.2	<0.0001
Non-smoker or Ex-smoker	327	89.1	59.2	
Histology				
Adenocarcinoma	245	66.8	62.3	<0.0001
Squamous cell carcinoma	100	27.2	48.8	
Others	22	6.0	11.9	
Clinical T				
Clinical T1	214	58.3	62.4	0.0287
Clinical T2	153	41.7	47.2	
Comorbidity				
Yes	102	27.8	42.5	0.0007
No	265	72.2	61.0	
Operative procedure				
Lobectomy	245	66.8	53.8	0.9499
Limited resection	122	33.2	59.8	
Nodal dissection				
ND0-1	240	65.4	56.8	0.7616
ND2	127	34.6	53.7	
Pathological stage				
p-stage I	300	81.7	60.9	<0.0001
p-stage II or advanced	67	18.3	30.8	

ND, lymph node dissection; ND0, without lymph node dissection or lymph node sampling; ND1, intrapulmonary and hilar lymph node dissection; ND2, ND1 plus mediastinal lymph node dissection.

50 mm in diameter. Twenty-one patients (5.7%) had poor Eastern Cooperative Oncology Group performance status, and 102 patients (27.8%) were diagnosed with some type of comorbidity (summarized in Table 2) before surgery. Eighteen patients had two comorbidities and three patients had three comorbidities. The most common comorbidity was active smoking status within 1 month of surgery. Twenty-two patients (6.0%) had comorbid ischemic heart disease.

Analysis of Prognostic Factors

The 1-, 3-, and 5-year overall survival rates after surgery for octogenarian patients were 89.1%, 70.6%, and 55.7%, respectively, in c-stage I NSCLC cases, 91.6%,

TABLE 2. Details of Preoperative Comorbidity

Type of Comorbidity	No. of Patients	%
Smoking	40	10.9
Obesity	1	0.3
Cerebro-neural diseases	17	4.6
Chronic obstructive pulmonary disease	13	3.5
Interstitial pneumonitis	5	1.4
Ischemic heart disease	22	6.0
Renal disease	3	0.8
Liver cirrhosis	0	0.0
Diabetes mellitus	12	3.3
Anemia	0	0.0
Autoimmune diseases	1	0.3
Total	102	27.8

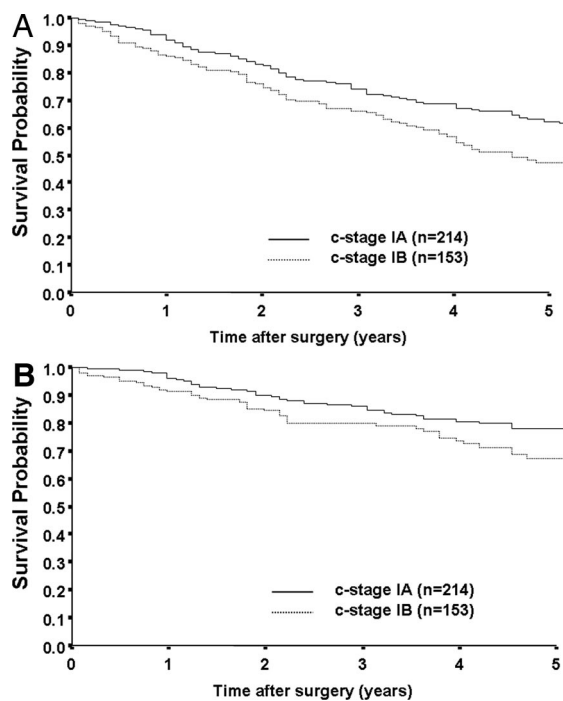


FIGURE 1. A, Postoperative overall survival curves according to the c-stage show a significant difference between c-stage IA and c-stage IB (p = 0.0287). B, Postoperative cause-specific survival curves according to the c-stage show a significant difference between c-stage IA and c-stage IB patients (p = 0.0440).

73.8%, and 62.0%, respectively, for c-stage IA, and 85.7%, 66.1%, and 47.2%, respectively, for c-stage IB (Figure 1A). Because 53 patients (15.0%) were lost to follow-up, they were censored at the date of last contact with the institution. One hundred forty-six patients died of causes listed in Table 3. Five operative mortalities occurred within 30 days of surgery, and 71 deaths from cancer were considered lung cancer-related. No patients in this cohort died during the same hospitalization later than 30 days after surgery, and 52 patients died of other causes during the 5-year follow-up period. The calculated cause-specific 5-year survival rate

TABLE 3. Summary of Causes of Death During 5-yr Follow-up

Cause of Death	No. of Patients	%	Percentage of all Deaths
Surgical mortality	5	1.4	3.4
Lung cancer-related death	71	19.3	48.6
Other cancer-related death	8	2.2	5.5
Died of nonmalignant diseases	44	12.0	30.1
Unknown	18	4.9	12.3
Total	146	39.8	100

after surgery was 73.4%, 77.9%, and 66.9% for c-stage I, stage IA, and stage IB patients, respectively (Figure 1B).

A univariate analysis was used to evaluate the prognostic impact of nine clinicopathological factors listed in Table 1. Female gender, non-smoker or ex-smoker, adenocarcinoma histology, c-T1, absence of comorbidity, and p-stage I were significant prognostic factors for greater overall survival. In addition, a good performance status (0 or 1) was marginally significant. Neither the surgical procedure (lobectomy or limited surgery) nor the extent of nodal dissection (ND0-1 or ND2) was significantly associated with survival. Adenocarcinoma was associated with a significantly better prognosis than squamous cell carcinoma or other carcinoma. A multivariate analysis showed that p-stage I and absence of comorbidity were independent significant beneficial factors for overall survival, whereas female gender, adenocarcinoma histology, and better performance status were marginally significant (Table 4).

Risk Factors for Postoperative Complications

A total of 31 patients (8.4%) presented with postoperative complications (Table 5). Two complications occurred in five patients. The most common complications in order of frequency were pneumonia followed by prolonged air leakage (>2 weeks). A multivariate analysis identified mediastinal lymph node dissection (ND2) and comorbidity as significant factors associated with increased risk of postoperative complications (Table 6). Interestingly, performance status, which is a well-recognized risk factor, was not significantly associated with postoperative complications. The reason for this could be that there was a very few percentage of the patients with a poor performance status.

TABLE 5. Details of Major Postoperative Complications

Type of Complication	No. of Patients	%
Pneumonia	17	4.6
Prolonged air leakage	7	1.9
Cerebral infarction	3	0.8
Empyema	2	0.5
Wound infection	1	0.3
Bronchopleural fistula	1	0.3
Pulmonary embolism	1	0.3
Respiratory failure	1	0.3
Myocardial infarction	1	0.3
Other	2	0.5
Total	31	8.4

Five patients (1.4%) died within 30 days of surgery, and each had undergone a lobectomy. Table 7 summarizes the clinical courses of these patients: four had (a) comorbid disease(s) with pneumonia in three patients, cerebral infarction in two, and myocardial infarction and pulmonary embolism in one patient. Thus, the operative mortality rate was 2.0% (five of 245) after lobectomy and zero after limited resection.

DISCUSSION

Surgery offers the highest probability of cure in all patients with early-stage lung cancer. However, surgeons often hesitate to recommend surgery for elderly patients because of the higher perioperative risks and the uncertainty of long-term benefit. As Japanese citizens who are 80 years old are expected to live for an additional 8.2 years for men and 11.1 years for women,² a radical treatment should be considered. More information regarding the short-term and long-term postoperative outcomes would help surgeons to select a subgroup of elderly patients suitable for a pulmonary resection. This study analyzed 367 patients aged from 80 to 90 years with c-stage I NSCLC. These patients accounted for 2.8% of all lung cancers in the registry.

The long-term results in this study were satisfactory. The 5-year survival rate was superior to those reported recently in a large cohort of octogenarians: 48% for p-stage IA and 39% for p-stage IB,¹⁰ although single institutional studies with smaller numbers of patients have presented

TABLE 4. Multivariate Analysis of Survival in Clinical Stage I Cases: Cox Proportional Hazard Model

Variable	Reference	HR	95% CI	p
Gender (female)	Male	0.691	0.466–1.027	0.067
Performance status (2 or 3)	0 or 1	1.829	0.977–3.423	0.059
Histology (non-adenocarcinoma)	Adenocarcinoma	1.390	0.966–2.000	0.076
Clinical T (cT2)	cT1	1.220	0.858–1.733	0.268
Operative procedure (limited resection)	Lobectomy	1.126	0.756–1.679	0.559
Nodal dissection (ND2)	ND0-1	1.093	0.747–1.598	0.648
Pathological stage (p-stage II or advanced)	p-stage I	2.149	1.471–3.141	<0.0001
Comorbidity (No)	Yes	0.678	0.475–0.966	0.032

HR, hazard ratio; CI, confidence interval; ND2, ND1 plus mediastinal lymph node dissection.

TABLE 6. Multivariate Analysis of Postoperative Complications in Clinical Stage I Cases: Logistic Regression Model

Variable	Reference	OR	95% CI	p
Factors in the final model				
Nodal dissection (ND2)	ND0-1	2.292	1.056–4.974	0.036
Comorbidity (Yes)	No	5.347	2.451–11.666	<0.0001
Factors not in the final model				
Gender (female)	Male	0.73	0.275–1.939	0.528
Performance status (2 or 3)	0 or 1	2.877	0.103–2.877	0.103
Histology (non-adenocarcinoma)	Adenocarcinoma	1.011	0.431–2.375	0.979
Operative procedure (limited resection)	Lobectomy	0.913	0.337–2.471	0.857
Clinical T (cT2)	cT1	1.455	0.626–3.380	0.384

OR, odds ratio; CI, confidence interval; ND2, ND1 plus mediastinal lymph node dissection.

TABLE 7. Clinical Background of Operative Mortalities

Case	Age	Gender	PS	c-Stage	Comorbidity	Surgery	Nodal Dissection	p-Stage	Postoperative Complications
1	82	Male	1	IA	Smoking, autoimmune disease	Lobectomy	ND2	IA	Cerebral infarction
2	81	Female	2	IA	Cerebro-neural disease	Lobectomy	ND1	IB	Myocardial infarction, pneumonia
3	80	Male	2	IB	Diabetes mellitus	Lobectomy	ND1	IB	Cerebral infarction, pneumonia
4	80	Male	0	IB	None	Lobectomy	ND0	IB	Pneumonia
5	80	Male	0	IB	Smoking, Interstitial pneumonitis	Lobectomy	ND2	IB	Pulmonary embolism

ND, lymph node dissection; ND0, without lymph node dissection or lymph node sampling; ND1, intrapulmonary and hilar lymph node dissection; ND2, ND1 plus mediastinal lymph node dissection; PS, Performance status.

better long-term survivals.^{7,8,18} There are several possible reasons for these differences. First, this study was limited to preoperative stage I patients. Second, the number of patients with a large tumor (≥ 50 mm in diameter) was less than that in the report citing lower survival rates.¹⁰ Third, as expected from the country with the world's highest life expectancy (78.5 years for men and 85.5 years for women²), Japanese octogenarians may have better physiological and medical conditions in comparison with the elderly in other countries.

A multivariate analysis identified p-stage and comorbidity status as significant factors influencing long-term survival. Although p-stage is a well-known prognostic factor, the role of comorbidity in prognosis is less clear.^{19,20} Any discussion of prognostic factors should consider that lung cancer-related deaths accounted for only 76 (52.1%) of the 146 deaths recorded in this study. Thus, comorbidity might influence the risk for death from causes other than lung cancer in elderly patients, as previously studied by Charlson et al.²¹ Of note, the 5-year lung cancer-specific survival rates in this study (77.9% for c-stage IA and 66.9% for c-stage IB) were almost equivalent to those for the general population in Japan.^{14,17} Surgeons should therefore consider comorbid diseases and preoperative staging in selecting those elderly patients most likely to achieve long-term benefit from pulmonary resection.

Postoperative complications were observed in 8.4% of the patients in this study. Comorbidity and mediastinal lymph node dissection (ND2) were identified as risk factors for increased postoperative complications by the multivariate analysis. Previ-

ous studies in elderly patients also proposed mediastinal lymph node dissection as a risk factor for postoperative complications.^{22,23} From the surgical point of view, recurrent nerve exposure, devascularization of the bronchial wall, and increased surgical exudates or bleeding due to mediastinal lymph node dissection are thought to be associated with several possible complications. However, this procedure is necessary for a complete resection in the patients with subclinical nodal diseases, accounting for 14.4% of the cohort in this study. Recently, advanced technologies such as 2-fluoro-2-deoxyglucose-positron emission tomography and endobronchial ultrasound-guided transbronchial needle aspiration have been available to evaluate hilar and mediastinal lymph nodes. These modalities could help in selecting the patients who can be cured without mediastinal lymph node dissection. In this regard, a more accurate preoperative staging may facilitate to decrease the postoperative complications.

The recommended surgical treatment for c-stage I patients is lobectomy and mediastinal lymph node evaluation.⁵ However, a limited resection and a lesser extent of lymph node dissection (ND0-1) were commonly performed in this study (limited resection in 33.2% and ND0-1 in 65.4% of patients) in comparison with the general population (limited resection in 4.7% and ND0-1 in 11.9%¹⁴). Although the reasons for selection of these procedures by the surgeons were not recorded in the registry, it is assumed that the surgeons intended to reduce the perioperative risks. Interestingly, the present study found no significant difference in the long-term survival of elderly patients between those who

underwent limited resection and lobectomy. This conflicts with a previous study from the Japan Lung Cancer Registry suggesting that lobectomy or pneumonectomy was a predictor of a good outcome for patients with stage I cancer in the general population.¹⁴ According to data from The National Cancer Registry in the United States,²⁴ lobectomies confer a significant survival benefit over limited resections, except in patients >71 years of age. Taken together, these findings implicate limited resection as an important alternative treatment for elderly patients with early-stage lung cancer despite lobectomy still being the ideal surgical option when the patient can tolerate the procedure. Consequently, minimizing surgical intervention in terms of both pulmonary resection and lymph node dissection should be considered to treat elderly patients with early-stage NSCLC as long as complete resection could be performed.

The operative mortality rate of 1.4% in this study was lower than those cited in recent studies with large sample sizes that described hospital mortality/30-day hospital mortality ranging from 2.2 to 8.8%.^{8,20} The rate in this study is also comparable with the mortality rate of lung cancer resection in the total population.^{17,25} Possible reasons for this low-mortality rate include the lower rate of patients with comorbid diseases and the higher proportion of patients undergoing less invasive surgery in this study.

Nonsurgical local therapies are currently used in the treatment of stage I lung cancer.^{26–29} In most cases, these therapies are indicated for high-risk patients unfit for surgery. Furthermore, recent technological advances have greatly improved the long-term results of these modalities with low treatment-related mortality. The benefits and the morbidity of surgery need to be carefully weighed against these less invasive approaches, especially in elderly patients. At present, there is little information available on comparison of these modalities with surgery with respect to overall survival rates and disease recurrence.³⁰ A clinical trial comparing the short- and long-term results of these different modalities would reliably help future surgical decision making with regard to treatment of local lung cancer in the elderly. Until such studies are performed, the results obtained in the present surgical series may constitute a basis on which to compare results.

The strengths of this study include the large sample size, the nationwide multi-institutional nature of the data, homogenous oncological status, minimum patients lost to follow-up, and the availability of complete pathologic findings. Limitations were that the study was retrospective, and that comorbidity status and postoperative complications were not described in detail. Several objective measurements can be used to evaluate and describe comorbidity and complications, as used in various previous studies.^{19,31–33} Such scoring systems enable comparison of the results among studies involving different patient backgrounds and treatment modalities. Activity of daily living and quality of life after surgery, not evaluated in this study, are also very important concerns for elderly patients and their family to consider when deciding to undergo surgery. In addition, the smoking history was not taken. If a patient quit smoking 1 month before surgery, the patient was categorized into a group of nonsmokers. This

was the reason why the percentage of current smokers was low (10.7%).

In summary, the long-term results of c-stage I NSCLC in octogenarians were satisfactory, with a 5-year survival rate of 55.7% for c-stage I, 62.0% for c-stage IA, and 47.2% for c-stage IB. Pathologic stage II or higher cancer and the presence of comorbidity were significantly independent factors predicting short survival, whereas comorbidity and mediastinal lymph node dissection (ND2) were independent risk factors for postoperative complications.

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