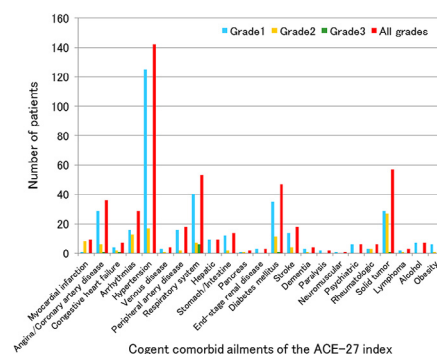


A Prospective Observational Study of Pulmonary Resection for Non–small Cell Lung Cancer in Patients Older Than 75 Years

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The operative morbidity rate in elderly patients with lung cancer is high in comparison to nonelderly patients, probably because of the increase in comorbidities that occurs with aging. However, previous reports were retrospective and were performed at single institutions; thus, the preoperative comorbidities and operative morbidity could not be fully assessed. We conducted a multi-institutional prospective observational study of elderly patients (>75 years of age) with a completely resected non–small cell lung cancer. From March 2014 to April 2015, 264 patients from 22 hospitals affiliated with the National Hospital Organization in Japan were prospectively registered in the present study. The primary end point was operative morbidity (National Cancer Institute Common Terminology Criteria for Adverse Events version 4.0). The secondary end points were operative mortality and the risk factors for operative morbidity. Preoperative comorbidities were assessed according to the Adult Comorbidity Evaluation–27 index. The mean age at the time of surgery was 79.3 years (range 75–90 years). Forty-one percent of the patients were >80 years of age. Twenty-six percent underwent sublobar resection. The incidence of morbidities of any grade was 43.2% (90% confidence interval: 38.2%–48.2%). Respiratory system-related morbidity (19.3%), followed by cardiovascular system-related morbidity (10.2%), was the most common morbidity.



Demographics of the preoperative comorbidities according to the ailments included in the ACE-27 index.

Central Message

The operative morbidity rate in this prospective multi-institutional study was 43.2% (90% confidence interval: 38.2%–48.2%). This should be a reference for elderly patients with lung cancer.

Perspective Statement

The rate of operative morbidity in elderly patients with lung cancer is high in comparison to nonelderly patients, probably because of the increase in comorbidities that occurs with aging. However, previous reports have been retrospective and single institutional, and both preoperative comorbidities and operative morbidities could not be fully assessed. We conducted a multi-institutional and prospectively observational study of elderly patients (>75 years of age) with a completely resected non–small cell lung cancer.

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The in-hospital mortality rate was 1.1% (3 of 264 patients). A multivariate analysis of the risk factors for operative morbidity showed that both Adult Comorbidity Evaluation-27 grade and the blood loss volume were significant factors. The results of the present prospective multi-institutional study should be used as a reference in the surgical treatment of elderly patients with lung cancer.

Keywords: non-small cell lung cancer, surgery, elderly patients, operative morbidity, operative mortality, ACE-27

INTRODUCTION

The aging of Japan's population is currently the most pronounced in the world. In this aging society, lung cancer, which has a mortality rate of 118.4 per 100,000 population in 2014 (Vital Statistics of Japan, by the Ministry of Health, Labor and Welfare), is the leading cause of cancer death. Accordingly, the lung cancer population is also aging. Despite advances in both chemotherapy and radiotherapy, surgical resection is still the standard treatment for early non-small cell lung cancer (NSCLC). According to the annual investigation of the Japanese Association for Thoracic Surgery in 2013,¹ more than half of the patients undergoing pulmonary resection for primary lung cancer in Japan were 70 years of age or older. Notably, 12.0% were 80 years of age or older.

According to the guidelines of both the American College of Chest Physician² and the European Respiratory Society of Thoracic Surgeons,³ chronological age alone is not a contraindication to surgery. Generally, even elderly patients with early NSCLC are indicated for surgical resection, when it is assessed that the patients will be able to physically tolerate surgical intervention. In most cases, similarly to younger patients, the selection criteria for surgery largely depend on both the patients' general performance status and their pulmonary function.⁴ On the other hand, probably because of the increase in comorbidities that occurs with aging, age has been reported to be an essential risk factor for pulmonary resection.⁵ It has recently been reported that the rates of operative morbidity and mortality in elderly patients with NSCLC range from 18.6% to 65.9% (mean: 37.1%) and from 0% to 4.5%, respectively.⁶⁻¹³ However, the previously reported results are from retrospective and single-institution studies. Thus, the influence of preoperative comorbidities on operative morbidity has not been fully clarified. This is an essential issue when surgery is considered in elderly patients. Furthermore, the definitions of both "elderly" and "operative morbidity" vary among the studies. Thus, the retrospectively reported results are difficult to use as a practical reference.

To resolve the above-mentioned issue, we conducted a multi-institutional and prospectively observational study of elderly (>75 years of age) patients with a completely resected NSCLC to examine the influence of preoperative comorbidities.

PATIENTS AND METHODS

Patients

The inclusion criteria for the patients of the present study were as follows: (1) the patient had a histologically confirmed NSCLC; (2) the patient had a complete resection, including ipsilateral pulmonary metastasis and R0 (un); and (3) the patient was >75 years of age at the time of surgery.

Study Design

Twenty-two hospitals affiliated with the National Hospital Organization in Japan participated in the present prospective

observational study. All of the hospitals are authorized by The Japanese Board of General Thoracic Surgery. The study protocol was approved by the Ethical Committee for Clinical Research of the National Hospital Organization; the participants were given the option of opting out (approval number: H26-0114002).

Before surgery, patients who were expected to meet the inclusion criteria were registered through the Electronic Data Capture system at the data center in the National Hospital Organization Kyushu Cancer Center. From March 2014 to April 2015, 314 preoperative patients were tentatively registered. Of those preoperatively registered patients, 264 met the inclusion criteria for the present study after surgery. Patients were excluded for the following reasons: no diagnosis of NSCLC (n = 21), incomplete resection (n = 19), no surgery (n = 6), and other reasons (n = 1). The minimum number of patients required for the present study was 262; the statistical basis is stated in the "Statistical Analyses" section.

Data Collection

The data that were collected through the Electronic Data Capture system included the preoperative, intraoperative, and postoperative information.

The preoperative information included the following: (1) gender; (2) age; (3) height; (4) weight; (5) Karnofsky Performance Status (KPS); (6) clinical stage (cTNM classification); (7) smoking status; (8) comorbidities; (9) respiratory function (FVC, %FVC, FEV_{1.0}, FEV_{1.0}%, %FEV_{1.0}, %DLco); and (10) percutaneous oxygen saturation (SpO₂). Preoperative comorbidities were evaluated using the Adult Comorbidity Evaluation-27 (ACE-27) index, which has been used in the risk assessment for various cancer treatments.^{14,15} The ACE-27 index includes 26 systemic comorbidities (cardiovascular system [n = 7], respiratory system [n = 1], gastrointestinal system [n = 3], renal system [n = 1], endocrine system [n = 1], neurologic system [n = 4], psychiatric [n = 1], rheumatologic [n = 1], immunologic system [n = 1], malignancy [n = 3], substance abuse [n = 2], and body weight [n = 1]), the severity of which were individually graded from 0 to 3 (1, mild; 2, moderate; and 3, severe). The patients were classified according to the highest grade of any comorbidity (<http://siog.org/files/public/ace27.pdf>). In the present study, the existence of clinically identified interstitial pneumonia was added to the ACE-27 index as a grade 2 (moderate) comorbidity.

The intraoperative information that was included was as follows: (1) date of surgery; (2) operative procedure (type of resection, performance of lymph node dissection, and thoracoscopic approach); (3) blood loss volume; (4) performance of blood transfusion; (5) operation time; and (6) intraoperative complications. To manage the postoperative condition of the patients, both a complete blood count and serum chemistry analyses were routinely conducted postoperatively in all of the hospitals participating in the present study.

The postoperative information that was included is as follows: (1) the pathologic diagnosis of the surgical specimen, (2) the

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