

Scientific Article

Feasibility of definitive chemoradiation therapy with nedaplatin and 5-fluorouracil in elderly patients with esophageal squamous cell carcinoma: A retrospective study

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Abstract

Purpose: This study was designed to retrospectively analyze the safety and efficacy of chemoradiation therapy with nedaplatin and 5-fluorouracil in elderly patients with esophageal squamous cell carcinoma.

Methods and materials: Eligible patients were aged 76 years or older, had a histopathologic diagnosis of esophageal squamous cell carcinoma, and were treated at the Kitasato University Hospital between January 2010 and March 2016. Chemotherapy consisted of nedaplatin in an intravenous dose of 90 mg/m² on day 1 and 5-fluorouracil in an intravenous dose of 800 mg/m² on days 1 to 5, repeated every 4 weeks for 2 cycles. Radiation therapy consisted of 50.4 Gy in 28 fractions for thoracic tumors and 61.2 Gy for cervical tumors.

Conflicts of interest: No conflicts of interest exist for any of the authors.

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Results: Twenty-five patients were studied. Patient characteristics were as follows: median age 79 years (range, 76-85 years), clinical stage I/II/III/IV (7/8/8/2, respectively), and surgically resectable/unresectable (17/8, respectively). The completion rates of radiation therapy and chemoradiation therapy were 100% and 84%, respectively. Grade ≥ 3 acute toxicities included neutropenia (76%), leukopenia (72%), thrombocytopenia (32%), anemia (28%), anorexia (32%), oral mucositis (20%), febrile neutropenia (12%), and esophagitis (8%). Grade ≥ 3 late toxicities included esophageal stenosis (12%) and pleural effusion (4%). The complete response rate was 64%. In the median follow-up period of 18.9 months, the 1-year overall survival rate was 68%.

Conclusions: Definitive chemoradiation therapy with nedaplatin and 5-fluorouracil may be a feasible treatment option for elderly patients with esophageal squamous cell carcinoma.

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Introduction

Esophageal cancer is a life-threatening disease and the number of patients in Japan has been increasing due to the rapid growth of the elderly population. Most cases of esophageal cancer develop in patients in their 60s to 70s and are advanced at the time of diagnosis. Among the estimated 21,965 new cases of esophageal cancer diagnosed in 2012 in Japan, 7497 (34.1%) were in elderly patients who were ≥ 75 years of age.¹

In Japan, the standard treatment for resectable advanced esophageal cancer is neoadjuvant chemotherapy followed by esophagectomy with 3-field lymph-node dissection. Chemoradiation therapy is also a curative treatment option for localized esophageal cancer, and 5-fluorouracil and cisplatin have been designated as key drugs.^{2,3} However, clinical trials supporting these standard treatments did not include elderly patients because patients who were aged ≥ 76 years were not eligible. In addition, outcomes after esophagectomy in elderly patients remain controversial.⁴⁻⁶ Moreover, a retrospective study reported that elderly patients with esophageal cancer had substantial morbidity from chemoradiation therapy, and long-term survival was low.⁷ Thus, the standard regimen of chemoradiation therapy for elderly patients with esophageal cancer remains to be established, and new treatment options with lower toxicity and higher efficacy must be developed.

Nedaplatin is a novel second-generation platinum compound that has shown promising antitumor activity with less nephrotoxicity, gastrointestinal toxicity, and neurotoxicity than cisplatin in some preclinical and clinical studies.⁸⁻¹² The combination of nedaplatin and 5-fluorouracil showed promising results in a phase 2 study of metastatic esophageal cancer.¹³ Moreover, a phase 1/2 study of definitive chemoradiation therapy with nedaplatin and 5-fluorouracil in patients with T4 disease showed that this regimen is active with acceptable toxicity.¹⁴ On the basis of these findings, nedaplatin seemed to be a new, less toxic anticancer drug in Japan.

We used nedaplatin and 5-fluorouracil combined with radiation therapy to treat esophageal squamous cell

carcinoma in elderly patients who were aged ≥ 76 years. To our knowledge, this is the first report to describe the results of a retrospective study evaluating the safety and efficacy of chemoradiation therapy with nedaplatin and 5-fluorouracil in elderly patients with esophageal squamous cell carcinoma.

Methods and materials

Patients

Between January 1, 2010 and March 31, 2016, a total of 25 patients with esophageal squamous cell carcinoma who were aged ≥ 76 years received definitive chemoradiation therapy with nedaplatin and 5-fluorouracil at our hospital. No patient with esophageal adenocarcinoma received this treatment. In patients with surgically resectable disease, we initially considered surgery-based treatments. However, if surgery was not performed because of the patient's refusal, poor performance status, or poor general condition, we administered chemoradiation therapy.

Endpoints

To assess safety, we retrospectively analyzed compliance with chemoradiation therapy, acute toxicity, and late toxicity. To assess effectiveness, we calculated complete response rates and overall and progression-free survival rates. To assess quality of life, we analyzed dysphagia scores. The dysphagia score was defined as 0 (able to eat a normal diet), 1 (unable to swallow certain solids), 2 (able to swallow semi-solid foods), 3 (able to swallow liquids only), and 4 (unable to swallow liquids).¹⁵ This retrospective study was approved by the ethics committee of our hospital.

Radiation therapy

Three-dimensional treatment planning was performed with the use of a computed tomography (CT) simulator.

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