A Phase II Study of Nedaplatin and Paclitaxel for Patients with Previously Untreated Advanced Squamous Cell Lung Cancer

Y. Yamada1, T. Kaburagi1, T. Kasai2, Y. Kamiyama3, T. Sugiyama2, K. Mori4
1Department of Respiratory Medicine, Ibaraki Prefectural Central Hospital, Kasama, JAPAN
2Medical Oncology, Tochigi Cancer Center, Utsunomiya, JAPAN
3Department of Medical Oncology, Tochigi Cancer Center, Utsunomiya, JAPAN
4Division of Thoracic Oncology, Tsuboi Cancer Center Hospital, Koriyama, JAPAN

Aim: Nedaplatin, a second-generation platinum derivative, is efficacious in the treatment of non-small cell lung cancer (NSCLC), especially squamous cell carcinoma. Previous studies investigating a combination of nedaplatin and paclitaxel (N/P) in the treatment of NSCLC showed promising outcomes, but there was no sufficient data in the treatment of squamous cell lung cancer. Here, we aimed to elucidate the efficacy and toxicity of N/P for previously untreated advanced squamous cell lung cancer.

Methods: The eligibility criteria were no prior chemotherapy; stage IIIb squamous cell lung cancer with no indications for radiotherapy or stage IV squamous cell lung cancer; a performance status (PS) of 0–1; age > 20 years; and adequate hematologic, hepatic, and renal function. Patients received nedaplatin (80 mg/m², day 1) and paclitaxel (90 mg/m², days 1 and 8) every 3 weeks. The primary endpoint was tumor response, which was measured using Response Evaluation Criteria in Solid Tumors 1.1. Tumor responses were confirmed by two extramural reviewers.

Results: Eighteen patients were enrolled in this study, and all were evaluable for toxicity and efficacy. The median patient age was 68 years (range, 49–77 years). Three and 15 patients had PS 0 and PS 1, respectively, and 7 and 11 patients had stage IIIb disease and stage IV disease, respectively. The median number of treatment cycles was 6 (range, 2–6). Complete response, partial response, and stable disease were noted in 1, 12, and 5 patients, respectively, yielding a response rate of 72.2% (95% confidence interval [CI]: 46.5–90.3). The median progression-free survival was 7.5 months (95% CI: 6.1–10.4), and the median survival time was 30.9 months (95% CI: 9.9–46.4). The grade 3 and 4 toxicities observed during all cycles were leukopenia (4 and 0 patients, respectively), anemia (4 and 1 patients, respectively), thrombocytopenia (2 and 1 patient, respectively), and neutropenia (8 and 2 patient, respectively). Although grade 2 pneumonitis occurred in 1 patient, there was no severe non-hematologic toxicity.

Conclusions: N/P appears to be safe and efficacious in patients with untreated advanced squamous cell lung cancer.

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