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An out-patient second-line chemotherapy with gemcitabine and vinorelbine in patients with non-small cell lung cancer previously treated with cisplatin-based chemotherapy. A phase II study of the Hellenic co-operative Oncology Group.

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Source

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Abstract

Thirty-nine patients with advanced non-small cell lung cancer, refractory or resistant to platinum or taxanes derivatives were treated on an out-patient basis with vinorelbine 25 mg/m2 intravenous (I.V.) on days 1 and 8 followed by gemcitabine 800 mg/m2 l.V. on days 1 and 8. Chemotherapy was repeated every 3 weeks. The patients were evaluated for response every two cycles of treatment. All 39 patients were assessable for toxicity and 35 were assessable for response. On an intent to treat analysis, only 1 (2.6%) patient achieved a partial response (PR) (95% CI 0.09% to 17.6%); fourteen patients (35.9%, 95% CI 29.45% to 67.4%) had stable disease (SD) and 24 (61.5%) had progressive disease (PD). The median time to tumor progression (TTP) was 4.7 months (range 0.13 to 18.9 months), the median survival time was 7.3 months (range 0.6 to 18.9 months) and the 1-year survival rate was 35%. Clinical benefit response including improvement of PS, dyspnea and anorexia, pain and cough reduction and cessation of hemoptysis and fever was observed in 10% to 50% of patients. Grade 3/4 neutropenia occurred only in 2 (5.2%) patients. Five patients experienced febrile neutropenia, which was successfully treated with G-CSF and broad-spectrum antibiotics. No patient experienced grade 3/4 anaemia or thrombocytopenia. One patient experienced grade 4 fatigue and stopped the treatment. Nausea / vomiting, fatigue, neurotoxicity, diarrhea and fever were mild in the majority of patients and did not result in any clinically significant problem. There were no treatment-related deaths. In conclusion, the combination of gemcitabine and vinorelbine showed low objective response rate in patients previously treated with CDDP/taxanes-containing regimens. This regimen was relatively well-tolerated and was associated with prolonged 1-year survival and improvement in cancer related symptoms. To validate these findings a randomized trial of gemcitabine and vinorelbine versus taxotere or best supportive care is required.