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PHASE II TRIAL OF GEMCITABINE AND PACLITAXEL COMBINATION CHEMOTHERAPY IN THE TREATMENT OF PATIENTS WITH RELAPSED OR REFRACTORY NON-SMALL CELL LUNG CANCER: West-Japan Thoracic Oncology Group (WJTOG0103DI)

T. Sawa, N.Katakami, H.Nishimura, K.Matsui, T.Seto, M.Fukuoka

Gifu Municipal Hospital, West-Japan Thoracic Oncology Group, Osaka, Japan

PURPOSE: A phase II trial was carried out to evaluate the efficacy and toxicity of combination chemotherapy of gemcitabine (GEM) and paclitaxel (PAC) in the treatment of patients with relapsed or refractory non-small cell lung cancer (NSCLC).

METHOD: Fifty-five patients with relapsed or refractory NSCLC who had received treatment with one or two previous regimen with platinum or docetaxel entered this multi-institutional clinical trial. Patients were assigned to either the CR/PR group or NC/PD group according to their last chemotherapy response . All patients received GEM 1000 mg/m^2 on day 1, 8 and PAC 150 mg/m^2 on day 1 of each 21-day cycle and repeated for more than 3 cycles.

RESULTS: Patients were evaluated for their response after each cycle of therapy. Those with objective response or stable disease continued treatment for three courses or until disease progression. In the 20 patients of CR/PR group, 4 of 19 valuable patients (21%) had partial responses to treatment. On the other hand, 1 of 33 valuable patients (3%) in the 35 patients of NC/PD group were observed to have a partial response. Median survival was 16 and 11 months, in the CR/PR and NC/PD group respectively. Treatment was generally well tolerated. Myelosuppression was the major toxicity.One patient developed pneumonitisthat resulted to treatment-related death.

CONCLUSION: The activity of GEM and PAC in patients with previously treated NSCLC is modest and is limited to patients with relapsed (chemotherapy-sensitive) disease. In patients with relapsed NSCLC treated with platinum or docetaxel, it is thought that this regimen provides an additional treatment option, with decreased toxicity when compared to other second-line options.

Keywords: gemcitabine, paclitaxel, non-small cell lung cancer