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CLINICAL REPORTS

Phase II study of docetaxel in combination with oxaliplatin in patients with metastatic or locally advanced esophagogastric cancer previously untreated with chemotherapy for advanced disease: results of the Central European Cooperative Oncology Group Study ESGAS.1.2.001

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Abstract

A phase II trial was performed to determine the efficacy and tolerance of docetaxel plus oxaliplatin with hematopoietic growth factor support in previously untreated patients with advanced gastroesophageal adenocarcinoma. Thirty-five patients were entered in this trial. Treatment consisted of 3-weekly docetaxel 80 mg/m² and oxaliplatin 100 mg/m² both infused on day 1. A prophylactic 5-day course of human granulocyte colony-stimulating factor 5 µg/kg/day was given subcutaneously, and erythropoietin (10 000 IU subcutaneously three times per week) was administered if hemoglobin was less than 12.0 mg/dl. The confirmed overall response rate was 34%, including two complete responses (6%) and 10 partial responses (28%). Fifteen patients (43%) had stable disease. The median time to response was 2.5 months (1–3.5), the median time to progression was 8.9 (4–42.5) months and the median overall survival time was 11.6 (2.5–51) months. Hematologic toxicity was common, though World Health Organization grade 3 or 4 neutropenia occurred only in six (17%) patients and anemia in six (17%) patients, respectively. Nonhematologic adverse reactions were usually mild-to-moderate. Our data suggest that the combination of docetaxel and oxaliplatin with granulocyte colony-stimulating factor and erythropoietin has a promising therapeutic index in patients with advanced gastroesophageal adenocarcinoma.

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