

Docetaxel and 5-FU in Patients with Advanced and Recurrent Gastric Cancer: phase II study

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Purpose: Previous studies have shown that docetaxel, a semisynthetic taxoid, has been shown to be active in patient with advanced gastric cancer. The Catholic University Gastric Cancer Study Group conducted a multicenter phase II trial of docetaxel and 5-FU in patients with advanced and recurrent gastric cancer. Primary endpoints were the response rate (RR), time to progression (TTP) and overall survival, secondary endpoint was toxicity of the regimen.

Patients and Methods: Between January 2003 and February 2004, 72 patients were recruited at 6 treatment centers, including 58 males: 14 females, advanced patients: recurrent patients, median age 54.5 years, performance status ECOG 0-2. Treatment consisted of docetaxel 60 mg/m² on day 1 and 5-FU 600 mg/m² on days 1 to 5 by continuous intravenous infusion, cycled every 21 days. tumor assessment was performed after finishing every two cycles of chemotherapy.

Results: A total of 284 courses of chemotherapy (median 3.9, range 1-9) were administered. Of 72 patients enrolled, all patients were evaluable for toxicity and 64 for response. Ten patients (15.6%) had a partial response, 15 patients (23.4%) had a stable disease and 39 patients (60.9%) had progressive disease for an overall RR of 15.6% (95% CI, 6.7 24.5). The RR was 23.5%(4/17) with liver metastasis and 16.7% (3/18) with lymph node metastasis. The grade III or IV toxicities occurred in 17 patients (23.6%) and the hematologic toxicities were most frequent, consisting of 10 leukocytopenia (13.9%), 2 neutropenia (2.7%)and 1 anemia (1.4%). The major nonhematologic toxicities were diarrhea, stomatitis, anorexia, chest pain, elevated liver enzyme, dyspepsia and GI bleeding. There was no treatment related death. The median TTP was 108 days (95% CI, 77 180), median overall survival was 289 days (95% CI, 193 419).

Conclusion: The combination of docetaxel and 5-FU provide appears both tolerable and active for patients with advanced or recurrent gastric cancer, especially with liver metastasis.