Feasibility study of biweekly capecitabine, oxaliplatin, and irinotecan in patients with untreated advanced gastric cancer

Emilio Bajetta, Elena Verzoni, Erminia Ferrario, Katia Dotti, Arpine Gevorgyan, and Luigi Celio

Medical Oncology Unit 2, Fondazione IRCCS Istituto Nazionale dei Tumori, Milan, Italy

ABSTRACT

Background. Capecitabine in combination with oxaliplatin and irinotecan (COI regimen) is active and well tolerated in metastatic colorectal cancer. Since there is no internationally adopted standard regimen, we have conducted a pilot study of COI in untreated advanced gastric cancer.

Methods. Patients received irinotecan, 180 mg/m² infused over 90 min on day 1, followed by oxaliplatin, 85 mg/m² in a 3-hr infusion on day 2, and capecitabine, 1000 mg/m²/day orally twice daily from days 2 to 6 of a biweekly schedule. Treatment was continued up to 8 cycles or until progression of disease occurred. Response (RECIST criteria) was assessed after the first three cycles and was to be confirmed at least 4 weeks following the first response.

Results. A total of 12 patients (5 men and 7 women) with a median age of 54 years (range, 42-65) was prospectively enrolled. Most of the patients (83%) had metastatic disease. Three complete responses, four partial responses and two disease stabilizations occurred in the intention-to-treat cohort, with an overall response rate of 58% (95% confidence interval, 28-85%). Median time to progressive disease and overall survival were 6.4 and 12 months, respectively. A total of 68 cycles was administered, with a median of 6 cycles per patient (range, 1-8). Grade 3 neutropenia occurred in two patients. The most common non-hematologic grade 3 toxicities were nausea (3 patients) and diarrhea (2 patients).

Conclusions. These preliminary findings suggest that biweekly COI is a feasible and promising triplet for the first-line treatment of advanced gastric cancer. A large multi-institutional phase II study of the combination has already been planned in this setting.

Key words: advanced, chemotherapy, gastric cancer, triplet.