

A PILOT PHASE II STUDY OF CHEMOTHERAPY WITH OXALIPLATIN, FOLINIC ACID, 5-FLUOROURACIL AND IRINOTECAN IN METASTATIC GASTRIC CANCER

Matteo Dalla Chiesa¹, Sebastiano Buti¹, Gianluca Tomasello¹, Federica Negri¹, Massimo Buononato², Antonio Brunelli², Silvia Lazzarelli¹, Matteo Brighenti¹, Gianvito Donati¹, and Rodolfo Passalacqua¹

¹Medical Oncology, ²Surgery Division, Azienda Istituti Ospitalieri di Cremona, Cremona, Italy

Aims and background: Previous phase II studies have reported that combinations of oxaliplatin, folinic acid and 5-fluorouracil or irinotecan, folinic acid and 5-fluorouracil are associated with good efficacy and an acceptable safety profile in metastatic gastric cancer. The aim of this study was to evaluate chemotherapy with oxaliplatin, folinic acid, 5-fluorouracil and irinotecan (COFFI regimen) in metastatic gastric cancer.

Methods: Patients received oxaliplatin (85 mg/m² d 1), irinotecan (140 mg/m² d 1), and L-folinic acid (200 mg/m² d 1) followed by 5-fluorouracil bolus (400 mg/m² d 1) and then 5-fluorouracil (2,400 mg/m² 48-h continuous infusion), every 14 days.

Results: Seventeen patients with metastatic gastric cancer were enrolled. Eight patients were pretreated for advanced disease. Of the 9 chemo-naïve patients, 8 were evaluated for response (1 patient was lost to follow-up): one complete re-

sponse, 5 partial responses and 2 progressions of disease occurred, giving an overall response rate, at intention-to-treat analysis, of 67%. Of the 8 pretreated patients, 6 were evaluated for response (2 patients had nonmeasurable disease): one partial response, 2 disease stabilizations and 3 progressions of disease occurred, giving an overall response rate, at intention-to-treat analysis, of 12%. Median progression-free and overall survival in chemo-naïve patients were 8.2 and 10.2 months, respectively, and in pretreated patients 2.7 and 3 months. Grade 3-4 neutropenia occurred in 55% of chemo-naïve patients. Thrombocytopenia, and anemia were observed in 18% and 29%, respectively. Grade 3 nausea/vomiting occurred in 12% and grade 3 diarrhea in 6%.

Conclusions: The COFFI regimen is active and well tolerated, therefore phase III studies are warranted.

Key words: 5-fluorouracil, folinic acid, irinotecan, metastatic gastric cancer, oxaliplatin.