

Phase II study of Capecitabine and Cisplatin for patients with metastatic Hepatocellular carcinoma

¹ Department of Internal Medicine, Cancer Research Institute, Seoul National University College of Medicine ² Department of Internal Medicine, Seoul National University College of Medicine, Seoul Korea ³ Department of Internal Medicine, Seoul National University Bundang Hospital, Seongnam, Korea

*Jeong-Ok Lee², Dae-Young Kim², Joo Han Lim², Myung-Deok Seo², Yi Hyeon gyu², Keun-Wook Lee^{1 3},
Do-Youn Oh^{1 2}, Jee Hyun Kim^{1 3}, Seock-Ah Im^{1 2}, Tae-You Kim^{1 2}, Yung-Jue Bang^{1 2}

Purpose : There is no standard chemotherapeutic regimen in HCC. Cisplatin and 5-fluorouracil (5-FU) showed modest antitumor activity in previous phase II study. We evaluated the efficacy and toxicity of the combination chemotherapy with capecitabine and cisplatin in patients with metastatic HCC. **Patients and Methods :** Between September 2003 and July 2007, we enrolled patients with metastatic HCC who had measurable lesions to this study in Seoul National University Hospital and Seoul National University Bundang Hospital. Patients received capecitabine 2g/m²/day with 2 weeks/1week on/off schedule, and cisplatin 60mg/m² on day 1 every 3 weeks. Antitumor response was evaluated every 2 cycles according to RECIST criteria and toxicity grading was assessed according to NCI CTC v3.0 Results Total 31 patients were enrolled. Male was 28(90.3%) and the median age was 56years (range 35-68). The majority of patients in this study had received prior treatment for HCC including transarterial chemoembolization (n=25), curative surgical resection (n=6), radiofrequency ablation(n=5), liver transplantation(n=4), percutaneous ethanol injection(n=3), etc. Objective response rate was 6.5%(n=2) and overall disease control rate was 29%(n=9). Median TTP was 8.4 weeks(95% CI 6.8-10.0) and OS was 56.7 weeks(95% CI 45.5-67.9). Progression free survival of 2 responders was 36.4 and 16.4 weeks. Grade 3/4 hematologic toxicities were thrombocytopenia(16.1%), neutropenia (6.5%) and anemia(3.2%) but there were no neutropenic fever and bleeding events. Grade 3/4 non-hematologic toxicities were elevated transaminases(12.9%), jaundice(3.2%) and mucositis(3.2%). There was no treatment-related mortality. The dose intensity of capecitabine was 86.3% and cisplatin 84.7%. After completion of chemotherapy, only 10 patients received supportive care and the others had other treatment modalities, 2nd line chemotherapy, local treatments(transarterial embolization, etc.) and palliative radiotherapy and so on **Conclusion :** Capecitabine and cisplatin combination chemotherapy in patients with metastatic HCC showed modest antitumor efficacy with tolerable toxicity

Irinotecan combined with infusional 5-FU and leucovorin for the treatment of metastatic or recurrent gastric cancer as the second-line chemotherapy.

Department of Internal medicine, Seoul National University College of Medicine

*Myung-Deok Seo, Keun-Wook Lee, Joo Han Lim, Hyeon Gyu Yi, Dae-Yung Kim, In Sil Choi, Byung Su Kim, Do-Youn Oh,
Jee Hyun Kim, Seock-Ah Im, Tae-You Kim, Yung-Jue Bang

Objective : In metastatic or recurrent gastric cancer (GC), few data are available on the efficacy or safety of Irinotecan combined with infusional 5-FU and leucovorin (FOLFIRI) regimen after progression following first-line chemotherapy. We analyzed efficacy and toxicity of FOLFIRI regimen as a second-line palliative chemotherapy in GC. **Methods :** Patients with metastatic or recurrent GC that failed platinum-based chemotherapy received FOLFIRI as a second-line treatment. FOLFIRI regimen consisted of irinotecan 180 mg/m² on day 1 combined with 2-hour infusions of leucovorin (200 mg/m²) followed by a 5-fluorouracil 400 mg/m² bolus and 22-hour continuous infusions (600 mg/m²) for two consecutive days every two weeks until progression or intolerable toxicity. **Results :** Sixty-one patients (median age 55 [range 29-79]; 46 male and 15 female) with documented progression on or within 6 months after discontinuing platinum-based chemotherapy were enrolled and received a total of 328 courses of chemotherapy (median 5; range 1-12). Nine patients (15%) achieved partial response. Stable disease was in 17 patients (28%), while progression was documented in 32 patients (52%). Three patients (5%) were not evaluable. Median progression-free survival was 3.0 months and median overall survival was 8.8 months, respectively. Of serious toxicities, grade 3 or 4 neutropenia was observed in 4 patients (7%), grade 3 diarrhea in 4 patients (7%) and grade 3 vomiting in 5 patients (8%). No treatment-related death occurred. **Conclusion :** FOLFIRI regimen showed moderate activity with favorable toxicity profiles for the treatment of GC as a second-line chemotherapy.