

A Phase II Study of Combination Chemotherapy with Gemcitabine, 5-Fluorouracil, and Cisplatin(GFP) for Advanced Pancreatic Cancer

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Objective: This study is aimed to assess the effectiveness and safety of combination chemotherapy with gemcitabine, 5-FU, cisplatin for advanced pancreatic cancer.

Methods and materials: Patients with advanced pancreatic cancer were entered into this study. Gemcitabine at a dose of 800 mg/m² on day 1 and 8, 5-FU 800 mg/m² from day 1 to 3 for 72 hours, cisplatin 60 mg/m² on day 2, 24hours after the start of gemcitabine were administered. This regimen was repeated every 3 weeks.

Results: From December 2001 to March 2009, 47 patients were enrolled in this study. Median age was 62 years (range 40-75). Among them, 37 patients were evaluable for their treatment response. 5 patients had a partial remission and the response rate was 13.5% (95% Confidence interval: 2.3-24.7%). The median time to disease progression and median duration of overall survival were 189 days and 302 days, respectively. Among total 158 cycles of treatment, grade 3 or 4 leukopenia, neutropenia and thrombocytopenia were observed in 32 cycles (20.3%), 44 cycles (27.9%) and 36 cycles (28.5%), respectively. Grade 3 or 4 mucositis was observed in 2 cycles (2.2%). Grade 3 or 4 nausea/vomiting was observed in 3 cycles (3.3%). No treatment related mortality was observed.

Conclusions: This regimen of gemcitabine, 5-FU, cisplatin for advanced pancreatic cancer is active and well-tolerated.