Phase II Study of Gemcitabine and UFT and Oral Calcium Folinate in Patients with Advanced Pancreatic Cancer


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**Background** Gemcitabine is useful as a single agent for pancreatic cancer. The combination of gemcitabine and 5-FU has been noted to have a marked synergistic effect in "in vitro" assays. Protracted infusion of 5-FU in combination with other agents showed interesting activity. Oral administration of UFT mimics protracted infusion of 5-FU without central venous catheter.

**Methods** Patients(pts) with biopsy proven locally advanced unresectable or metastatic disease with bidimensionally measurable lesion were eligible. Previous chemotherapy or radiation therapy was not allowed. Treatment, given in the outpatient setting, consisted of: Gemcitabine 800 mg/m$^2$ IV administered on days 1, 8, 15 of each cycle; UFT 200 mg/m$^2$/day and oral calcium folinate 90 mg/day PO on days 1 to 21 of each cycle. Cycles were repeated every 28 days. Pts were restaged after two cycles of chemotherapy.

**Results** Twenty six patients have been enrolled thus far, with 23 pts evaluable for objective tumor response and 25 for toxicity. Total number of cycles administered was 82, with a median of 3 (range 1-8). Pts’ characteristics included: Karnofsky performance status 60-70(14 pts) and 80-90(12 pts); median age 54.5 years(41-65); clinical stage III 2 and IV 24 pts. The grade III/IV toxicities were included leucopenia 6(7%), neutropenia 2(3%), thrombocytopenia 0, hepatotoxicity 1(1%). There was no treatment-related death. Three pts showed partial response, 11 pts showed stable disease, and 9 pts progressed after chemotherapy. The overall response for evaluable pts was 13% (95% CI: 0-27%). The median overall survival was 19 months (1-38) and 1-year survival rate was 43%.

**Conclusion** This combination chemotherapy regimen was well tolerated and showed moderate antitumor activity in the treatment of pancreatic cancer.