gastrointestinal tumours, non-colorectal

**FIXED DOSE RATE GEMCITABINE AND S-1 COMBINATION THERAPY (FGS) AS SALVAGE CHEMOTHERAPY FOR GEMCITABINE-REFRACTORY ADVANCED PANCREATIC CANCER**

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Aim: No standard salvage chemotherapy regimens has been established for patients with advanced pancreatic cancer after failure of gemcitabine-based treatment. Although a phase I/II clinical trial of FGS was conducted, the number of patients enrolled was small and the efficacy and safety of FGS is still not well known.

Methods: We retrospectively reviewed 67 patients who received FGS as salvage chemotherapy at our institution from March 2009 to Mach 2014. The selection criteria in this study was progressive disease under gemcitabine-based chemotherapy, ECOG performance status \( \leq 2 \) and preserved organ functions. Patients who had not received gemcitabine were excluded from the study. Gemcitabine was administered by fixed dose rate of 1200 mg/m² as a 120-min infusion on day 1 and S-1 was administered orally twice a day at a dose of 40 mg/m² on day 1 to 7. Cycles were repeated every 14 days.

Results: Sixty-six patients were selected for the analysis. Twenty-two patients of them had received FGS as third line treatment. The overall response rate was 12% and the disease control rate was 45%. The median progression-free survival time was 2.7 months and the median overall survival time was 6.0 months. The common grade 3/4 toxicities were leukopenia (11%), neutropenia (15%), diarrhea (3%), anorexia (2%) and fatigue (2%). Univariate analysis showed that performance status of \( > 0 \), presence of ascites, serum carcinoembryonic antigen level of \( > 10 \) ng/ml, serum albumin level of \( \leq 3.5 \) g/dl, serum alkaline phosphatase level of \( > 500 \) IU/L and serum C-reactive protein level of \( > 1.0 \) mg/dl were significantly associated with a poor prognosis. Multivariate analysis identified serum C-reactive protein level of \( > 1.0 \) mg/dl as factors independently associated with a poor prognosis.

Conclusions: FGS as salvage chemotherapy for patients with gemcitabine-refractory advanced pancreatic cancer is marginally effective and well tolerated in a practical setting. These results suggest FGS is of value to be further investigated in a clinical trial in patients with gemcitabine-refractory pancreatic cancer.

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