

### **A Phase II Study of S-1 in Elderly Patients with Unresectable Pancreatic Cancer**

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#### **Abstract**

**Background/Aims:** The aim of this study was to investigate the efficacy and safety of the oral fluoropyrimidine derivative S-1 in elderly patients with unresectable pancreatic cancer.

**Methods:** Patients were eligible if they were at least 70 years old and had unresectable pancreatic carcinoma. S-1 was administered orally twice daily after meals at doses of 80, 100, and 120 mg/day for body surface areas for 28 consecutive days, followed by a 14-day rest period. Administration was repeated until the appearance of disease progression or unacceptable toxicity.

**Results:** Twenty-one patients were enrolled in this study. Five patients (23.8%) achieved a partial response (95% CI, 8.2-47.2%), stable disease was observed in 9 patients (42.9%), and progressive disease was observed in 5 patients (23.8%). The disease control rate was 66.7%. The median time to progression and overall survival time were 3.7 months (95% CI, 2.3-6.5 months) and 7.3 months (95% confidence interval, 4.9-12.1 months), respectively. Toxicity was generally mild, and the most common grade 3/4 toxicities were neutropenia (14.3%), anemia (14.3%), leucopenia (9.5%), thrombocytopenia (9.5%), anorexia (9.5%), and diarrhea (9.5%). There were no treatment-related deaths.

**Conclusions:** Monotherapy with S-1 is an effective and well-tolerated regimen for elderly patients with unresectable pancreatic cancer.

**Key words:** pancreatic cancer, chemotherapy, elderly patients, S-1