Phase II trial of a 24-hour infusion of gemcitabine in previously untreated patients with advanced pancreatic adenocarcinoma.

Abstract:
The antitumor effect of gemcitabine is not dose-response related but schedule dependent. Here we report a phase II trial of a weekly 24-hour infusion of gemcitabine in previously untreated patients with advanced pancreatic cancer. Patients with histologically proven, measurable, and irresectable pancreatic adenocarcinoma were treated with gemcitabine at a dose of 100 mg/m² infused over 24 hr on days 1, 8, and 15. Treatment was repeated every 28 days until progression of disease or limiting toxicity. All 18 patients enrolled were evaluable for response. Neutropenia and thrombocytopenia grade 3 occurred in 1 patient each. One partial response and two minor responses were observed. Median time to progression of disease was 4.4 months. Improvement of the European Organization for Research and Treatment of Cancer C30 scores was observed in 6 patients (pain and overall symptom score, respectively) and in 3 patients (overall functioning score and global quality of life, respectively). Weekly 24-hr gemcitabine was well tolerated in previously untreated patients with advanced pancreatic cancer. It shows marginal antitumor activity in terms of response rate. However, the 24-hr infusion at a dose of 100 mg/m² seems to be as active as the standard 30-min gemcitabine at a dose of 1000 mg/m². Relatively long median time to progression of disease and improvement of symptom and
quality-of-life scores suggest, that patients may benefit from 24-hr gemcitabine.