Ann Oncol. 2003 Mar;14(3):388-94.

Treatment of pancreatic cancer with a combination of irinotecan (CPT-11) and gemcitabine: a multicenter phase II study by the Greek Cooperative Group for Pancreatic Cancer.

Stathopoulos GP, Rigatos SK, Dimopoulos MA, Giannakakis T, Foutzilas G, Kouroussis C, Janninis D, Aravantinos G, Androulakis N, Agelaki S, Stathopoulos JG, Georgoulias V; Greek Cooperative Group for Pancreatic Cancer.

Source

First Department of Medical Oncology, Errikos Dynan Hospital of Athens, Athens, Greece. dr-gps@ath.forthnet.gr

Abstract

BACKGROUND:

The efficacy and toxicity of gemcitabine (GEM) and irinotecan (CPT-11) is evaluated in previously untreated patients with inoperable or metastatic pancreatic cancer.

PATIENTS AND METHODS:

From January 1999 to July 2001, 60 patients with pancreatic cancer (85% stage IV) were enrolled in a two-step extended phase II trial. Patients were treated with gemcitabine (1,000 mg/m2 on days 1 and 8) and CPT-11 (300 mg/m2 on day 8) in cycles of 3 weeks. No prophylactic use of recombinant human granulocyte colony-stimulating factor (rhG-CSF) was initially planned.

RESULTS:

In an intention-to-treat analysis one (1.7%) complete and 14 (23.3%) partial responses were achieved [objective response rate (ORR) 24.7%; 95% confidence interval 14.04% to 35.96%]. Twenty-two (36.7%) and 23 (38.3%) patients had stable and progressive disease, respectively. The median duration of response was 5 months, the median time to tumor progression (TTP) was 7 months and the median overall survival 7 months. One-year survival was 22.5%. Pain improvement and asthenia during treatment were observed in 45% and 43% of patients, respectively; weight gain occurred in 19.5% of patients. Grade 3 anemia occurred in three (5%) patients who required transfusion of six packed red blood cell (RBC) units. Ten (16.7%) additional patients with grade 2 anemia were treated with recombinant erythropoietin. Grade 3 thrombocytopenia occurred in seven (11.7%) patients and grades 3 and 4 neutropenia in 27 (45%). Ten patients developed febrile neutropenia, two of whom died due to sepsis. Prophylactic use of rhG-CSF was eventually required in 93 (28.3%) of 329 administered cycles. Other toxicities were mild.

CONCLUSIONS:

The combination of gemcitabine and irinotecan is an active chemotherapy regimen against pancreatic cancer with a 25% ORR. Toxicity was acceptable for the great majority of patients but with a high percentage of hematopoietic growth factor administration.