Front-line treatment of inoperable or metastatic pancreatic cancer with gemcitabine and capecitabine: an intergroup, multicenter, phase II study.

Stathopoulos GP, Syrigos K, Polyzos A, Fountzilas G, Rigatos SK, Ziras N, Potamiannou A, Tsiakopoulos I, Androulakis N, Aravantinos G, Athanasiadis A, Papakotoulas P, Georgoulias V.

Source

Hellenic Oncology Research Group, Athens, Greece. dr-gps@ath.forthnet.gr

Abstract

PURPOSE:

To evaluate the efficacy and toxicity of gemcitabine (GEM) combined with capecitabine (CAP) in untreated patients with inoperable or metastatic pancreatic cancer.

PATIENTS AND METHODS:

Fifty-three patients with pancreatic cancer (85% stage IV) were enrolled. Patients were treated with GEM 1000 mg/m2 on days 1 and 8 and CAP 1300 mg/m2 per day PO (per os), divided into two equal doses on days 1-14, in 21-day cycles.

RESULTS:

In an-intention-to-treat analysis, 10 (18.9%) objective partial responses were achieved (95% confidence interval 8.33% to 29.4%). Twenty-two (42%) patients had stable disease and 15 (28%) had progressive disease. The median response time was 3 months (range 1.5-7.0) and the median time to tumor progression was 6.5 months (range 3.5-15.5). Median overall survival time was 8 months (range 1.0-15.5) and 1-year survival was 34.8%. Pain improvement during treatment was observed in 23 of 43 (53%) patients, and eight of 18 (44%) patients who had been receiving opioids discontinued their use. Weight gain was observed in 12 of 33 (36%) patients. Grade 3 anemia occurred in five (9%) patients and grade 3-4 thrombocytopenia occurred in three (6%). Grade 3-4 neutropenia occurred in 13 (25%) and five (9%) patients, respectively, and two (4%) developed febrile neutropenia. Non-hematological toxicity was mild.

CONCLUSION:

In patients with pancreatic cancer, the combination of GEM with CAP is an active and well tolerated regimen that merits further evaluation in prospective randomized studies.