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Carboplatin plus gemcitabine in patients with inoperable or metastatic pancreatic cancer: a phase II multicenter study by the Hellenic Cooperative Oncology Group.

[Xiros N](#), [Papacostas P](#), [Economopoulos T](#), [Samelis G](#), [Efstathiou E](#), [Kastritis E](#), [Kalofonos H](#), [Onyenadum A](#), [Skarlos D](#), [Bamias A](#), [Gogas H](#), [Bafaloukos D](#), [Samantas E](#), [Kosmidis P](#).

Source

Second Department of Internal Medicine, Propaedeutic and Research Institute, University General Hospital 'Attikon', University of Athens, Greece. nxiros@otenet.gr

Abstract

BACKGROUND:

In the present phase II multicenter study, we assessed the efficacy and tolerability of the combination of gemcitabine and carboplatin in patients with advanced pancreatic cancer.

PATIENTS AND METHODS:

Patients with previously untreated, locally advanced or metastatic pancreatic cancer were treated with gemcitabine 800 mg/m² on days 1 and 8 and carboplatin at an AUC of 4 on day 8 of a 3-week cycle, for a total of six cycles. Primary end points were response rate and clinical benefit; secondary end points were, survival, time to progression (TTP) and toxicity.

RESULTS:

A total of 50 patients were enrolled in the study, 47 of whom were eligible for treatment. The median age was 63 years (range 34-76) and the median Karnofsky performance status (PS) was 80%. Patients received a median of six cycles (range 1-11). Among 35 patients evaluable for response, eight (17%) achieved partial response; 15 (32%) and 12 (25%) patients had stable and progressive disease, respectively. The median overall survival was 7.4 months; the median TTP was 4.4 months and the 1-year survival was 28%. The observed clinical benefit response was remarkable. After the second cycle of chemotherapy, 21 of 31 (68%) patients experienced pain improvement and reduced analgesic consumption. At the same time, 35% and 56% of our patients significantly improved their Karnofsky PS and weight, respectively. Overall, the treatment was well tolerated. The most common grade 3-4 toxicities were hematological, including 8% anemia, 6% neutropenia and 13% thrombocytopenia.

CONCLUSIONS:

The combination of gemcitabine plus carboplatin is a moderately active treatment for patients with locally advanced and metastatic pancreatic cancer. This regimen has an acceptable toxicity profile and provides a significant clinical benefit, and hence warrants further investigation.