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The combination of gemcitabine and carboplatin as first-line treatment in patients with advanced urothelial carcinoma. A Phase II study of the Hellenic Cooperative Oncology Group.

[Bamias A](#), [Moulopoulos LA](#), [Koutras A](#), [Aravantinos G](#), [Fountzilias G](#), [Pectasides D](#), [Kastritis E](#), [Gika D](#), [Skarlos D](#), [Linardou H](#), [Kalofonos HP](#), [Dimopoulos MA](#).

Source

Department of Clinical Therapeutics, Athens University, School of Medicine, Athens, Greece.
abamias@med.uoa.gr

Abstract

BACKGROUND:

The toxicity of platinum-based combinations represents a common problem for patients with advanced urothelial carcinoma. The authors previously reported encouraging efficacy for the combination of carboplatin and gemcitabine in patients considered to be unfit for cisplatin-based treatment. The objective of the current multicenter Phase II study was to evaluate the safety and efficacy of the combination of gemcitabine and carboplatin as first-line treatment in unselected patients with advanced urothelial carcinoma.

METHODS:

Patients with previously untreated, bidimensionally measurable, inoperable or metastatic urothelial carcinoma were treated with carboplatin, area under the concentration curve of 5 (Day 1) and gemcitabine at a dose of 1000 mg/m² (Days 1 and 8), every 21 days for a total of 6 cycles.

RESULTS:

Sixty patients (49 men and 11 women, with a median age of 69 yrs) were enrolled in the current study. Intent-to-treat analysis demonstrated an objective response rate (ORR) of 38.4% (95% confidence interval [95% CI], 26-51.8%) (11.7% complete responses and 26.7% partial responses). The median time to disease progression was 7.6 months (95% CI, 4.5-10.7 mos) and the median overall survival was 16.3 months (95% CI, 12-20.6 mos). The median survival was comparable to that reported for the combination of methotrexate, vinblastine, doxorubicin, and cisplatin (M-VAC) according to the Memorial Sloan-Kettering Cancer Center prognostic model for patients with similar baseline prognostic features. Grade 3 or 4 toxicity (according to the National Cancer Institute Common Toxicity Criteria [version 2.0]) included anemia (18%), thrombocytopenia (23%), and neutropenia (52%), with 7 episodes of febrile neutropenia (11%) reported. Nonhematologic toxicity was rare. One toxic death occurred during the study.

CONCLUSIONS:

The combination of gemcitabine and carboplatin appears to have considerable activity as the first-line treatment of unselected patients with advanced urothelial carcinoma with manageable toxicity, and deserves further evaluation in this setting.