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Docetaxel and cisplatin combination chemotherapy in advanced carcinoma of the urothelium: a multicenter phase II study of the Hellenic Cooperative Oncology Group.

[Dimopoulos MA](#), [Bakoyannis C](#), [Georgoulas V](#), [Papadimitriou C](#), [Moulopoulos LA](#), [Deliveliotis C](#), [Karayannis A](#), [Varkarakis I](#), [Aravantinos G](#), [Zervas A](#), [Pantazopoulos D](#), [Fountzilas G](#), [Bamias A](#), [Kyriakakis Z](#), [Anagnostopoulos A](#), [Giannopoulos A](#), [Kosmidis P](#).

Source

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Abstract

PURPOSE:

Both docetaxel and cisplatin have moderate activity in patients with advanced urothelial cancer. We performed a multicenter phase II study in order to assess the efficacy and toxicity of the combination of these two agents in patients with advanced carcinoma of the urothelium.

PATIENTS AND METHODS:

Sixty-six patients not amenable to curative surgery or irradiation were enrolled onto this cooperative group study and treated on an outpatient basis with docetaxel 75 mg/m² followed by cisplatin 75 mg/m², both administered intravenously. Granulocyte-colony stimulating factor was administered subcutaneously at a dose of 5 micrograms/kg daily from day 5 until resolution of neutropenia. The chemotherapy was administered every three weeks for a maximum of six courses in patients without evidence of progressive disease.

RESULTS:

Thirty-four of sixty-six patients (52%, 95% confidence interval 40%-64%) demonstrated objective responses, with eight achieving clinical complete responses and twenty-six partial responses. A multivariate logistic regression analysis indicated that the patients most likely to respond were those without lung metastasis and without weight loss before treatment. The median duration of response was 6.1 months and the median times to progression and survival for all patients were 5 and 8 months, respectively. Absence of anemia, of liver metastases and of weight loss correlated with longer survival. Grade \geq 3 toxicities included granulocytopenia in 33% of patients, anemia in 14%, diarrhea in 13% and emesis in 7% of patients.

CONCLUSION:

The combination of docetaxel and cisplatin appeared relatively well tolerated and moderately active in patients with advanced urothelial cancer. The patients most likely to benefit were those without weight loss and without lung or liver metastases.