

Gemcitabine and carboplatin combination as first-line treatment in elderly patients and those unfit for cisplatin-based chemotherapy with advanced bladder carcinoma: Phase II study of the Hellenic Co-operative Oncology Group.

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Source

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Abstract

OBJECTIVES:

To evaluate, in a multicenter Phase II study, the safety and efficacy of the combination of gemcitabine and carboplatin, as first-line treatment in elderly and unfit patients with advanced bladder carcinoma. The toxicity of platinum-based chemotherapy combinations represents a common problem for elderly or unfit patients with advanced bladder carcinoma.

METHODS:

Patients with previously untreated inoperable or metastatic bladder carcinoma and an Eastern Cooperative Oncology Group performance status greater than 2, age older than 75 years, or creatinine clearance of less than 50 mL/min were treated with carboplatin area under the curve 4 on day 1 and gemcitabine 1000 mg/m² on days 1 and 8, every 21 days for a total of six cycles.

RESULTS:

A total of 56 patients (48 men and 8 women, median age 75 years) were enrolled. Of these patients, 46% had a performance status of 2 to 3, 68% had a creatinine clearance of less than 50 mL/min, and 59% had distant metastases. The overall response rate was 36% (95% confidence interval 23.4% to 49.6%), and an additional 14 patients had disease stabilization (25%, 95% confidence interval 14.4% to 38.4%). The median time to progression was 4.8 months, the median overall survival was 7.2 months, and the 1-year survival rate was 26%. Grade 3 or 4 toxicity included anemia (18%); thrombocytopenia (16%); neutropenia (27%), with two episodes of febrile neutropenia requiring hospitalization; diarrhea (2%); and fatigue (5.5%). Two toxic deaths occurred during the study.

CONCLUSIONS:

The combination of gemcitabine and carboplatin has some activity as first-line treatment of advanced bladder carcinoma in the elderly and those unfit for cisplatin-based chemotherapy, with manageable toxicity, and represents a reasonable choice for the treatment of such patients.