Docetaxel and cisplatin with granulocyte colony-stimulating factor (G-CSF) versus MVAC with G-CSF in advanced urothelial carcinoma: a multicenter, randomized, phase III study from the Hellenic Cooperative Oncology Group.

Bamias A, Aravantinos G, Deliveliotis C, Bafaloukos D, Kalofonos C, Xiros N, Zervas A, Mitropoulos D, Samantas E, Pectasides D, Papakostas P, Gika D, Kourousis C, Koutras A, Papadimitriou C, Bamias C, Kosmidis P, Dimopoulos MA; Hellenic Cooperative Oncology Group.

Source

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Abstract

PURPOSE:

The combination of methotrexate, vinblastine, doxorubicin, and cisplatin (MVAC) represents the standard regimen for inoperable or metastatic urothelial cancer, but its toxicity is significant. We previously reported a 52% response rate (RR) using a docetaxel and cisplatin (DC) combination. The toxicity of this regimen compared favorably with that reported for MVAC. We thus designed a randomized phase III trial to compare DC with MVAC.

PATIENTS AND METHODS:

Patients with inoperable or metastatic urothelial carcinoma; adequate bone marrow, renal, liver, and cardiac function; and Eastern Cooperative Oncology Group performance status < or = 2 were randomly assigned to receive MVAC at standard doses or docetaxel 75 mg/m(2) and cisplatin 75 mg/m(2) every 3 weeks. All patients received prophylactic granulocyte colony-stimulating factor (G-CSF) support.

RESULT:

Two hundred twenty patients were randomly assigned (MVAC, 109 patients; DC, 111 patients). Treatment with MVAC resulted in superior RR (54.2% v 37.4%; P =.017), median time to progression (TTP; 9.4 v 6.1 months; P =.003) and median survival (14.2 v 9.3 months; P =.026). After adjusting for prognostic factors, difference in TTP remained significant (hazard ratio [HR], 1.61; P =.005), whereas survival difference was nonsignificant at the 5% level (HR, 1.31; P =.089). MVAC caused more frequent grade 3 or 4 neutropenia (35.4% v 19.2%; P =.006), thrombocytopenia (5.7% v 0.9%; P =.046), and neutropenic sepsis (11.6% v 3.8%; P =.001). Toxicity of MVAC was considerably lower than that previously reported for MVAC administered without G-CSF.

CONCLUSION:

MVAC is more effective than DC in advanced urothelial cancer. G-CSF-supported MVAC is well tolerated and could be used instead of classic MVAC as first-line treatment in advanced urothelial carcinoma.