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Combination chemotherapy with gemcitabine and ifosfamide as second-line treatment in metastatic urothelial cancer. A phase II trial conducted by the Hellenic Cooperative Oncology Group.

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Source

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Abstract

PURPOSE:

The aim of the study was to evaluate the efficacy and safety of the combination of gemcitabine and ifosfamide as a second-line treatment for advanced urothelial cancer.

PATIENTS AND METHODS:

Thirty-four patients with metastatic urothelial cancer previously treated with cisplatin (CDDP)/ carboplatin (CBDCA) and/or taxanes-based chemotherapy were studied. Gemcitabine was administered at a dose of 800 mg/m2 on days 1 and 8 and ifosfamide at a dose of 2 g/m2 on days 1 and 8 with adequate amount of Mesna. every three weeks. Hematopoietic growth factors were given between days 3 to 5 and 12 to 16 to maintain the treatment schedule.

RESULTS:

On an intent to treat basis, there was one complete response (CR) (3%) (95% confidence interval (95% CI): 0% to 10%) and six partial responses (PR) (18%) (95% CI: 7% to 34%). inducing an objective response rate (RR) of 21% (95% CI: 9% to 38%); 12 (35%) patients achieved a stable disease (SD) and 15 (44%) a progressive disease (PD). The median time to tumor progression (TTP) was four months (range, 0.52 to 21.6 months) and the median survival nine months (range 0.52 to 28 months). This regimen also provided the opportunity for symptomatic improvement of pain, dysuria, haematuria and leg oedema. Grade 3-4 neutropenia was experienced by 9 (27%) patients, grade 3 4 anemia by 6 (18%) and grade 3-4 thrombocytopenia by 4 (12%). Six patients were hospitalized due to febrile neutropenia. Despite the prophylactic use of hematopoietic growth factors, 8 (23.5%) patients required dose reduction due to myelosuppression. Grade 3 alopecia occurred in 14 (41%) patients, grade 3-4 nausea in 1 (3%), grade 2 fever in 3 (9%), grade 2-3 diarrhea in 2 (6%) and grade 2 allergic reaction in 1 (3%).

CONCLUSION:

We conclude that the combination of gemcitabine and ifosfamide is an active salvage regimen for the treatment of urothelial cancer and that the treatment also has a tolerable toxicity profile; it warrants further investigation in combination with CDDP in chemotherapy-naïve patients.