5-Fluorouracil, interferon-alpha-2b and cisplatin (FAP) for advanced urothelial cancer. A phase II study. Hellenic Co-operative Oncology Group.

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Source

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Abstract

PURPOSE:

To evaluate the efficacy and toxicity of the FAP combination chemotherapy as first-line treatment in advanced urothelial cancer.

PATIENTS AND METHODS:

Thirty-four patients with histologically confirmed advanced urothelial cancer, with measurable disease and without previous chemotherapy entered the study; all 34 are evaluable. The 28 males and 6 females had a median age of 65 (19-75) and a median ECOG performance status of 1 (0-2). Twenty-eight patients had bladder cancer, four had renal pelvic cancer and two ureteral cancer. Thirty patients had transitional cell carcinoma and four mixed, mostly of grade 3. Sites of disease included lymph nodes (18), bladder (9), liver (9), pelvic mass (9), lung (7), etc. The treatment plan was as follows: 5-fluorouracil 500 mg/m2 continuous infusion D1-D5 and D22-D26; interferon-alpha-2b 5 million i.u./m2 D1-D5 followed by 3x/week and then D22-D26; cisplatin 25 mg/m2 D1, D8, D15, D22. Cycles were repeated every 36 days.

RESULTS:

The median number of cycles administered was 3 (1-6). The relative dose intensities for 5-fluorouracil, interferon and cisplatin were 76%, 71% and 75%, respectively. Twenty-two of 34 patients (65%, 95% confidence interval [95% CI], 46% to 80%) had objective responses, including six complete clinical responses (CR) (18%, 95% CI, 7% to 35%) and 16 partial responses (PR) (47%, 95% CI, 30% to 65%). Three patients had stable disease and seven progressed. Two patients discontinued treatment after the first cycle because of toxicity. The median survival is 15.30 months (1.40-37.60), the median time to progression 11.60 months (4.13-37.60), and the median survival of complete responders 20.75+ months (8+ to 38+). The only significant hematologic toxicity was the grade 3-4 neutropenia in 44%. Non-hematologic toxic effects were unremarkable.

CONCLUSION:

The FAP combination as first-line chemotherapy is highly active in the treatment of advanced urothelial cancer, and has limited toxicity. Further phase III studies are in progress to compare FAP and M-VAC.