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The combination of estramustine and mitoxantrone in hormone-refractory prostate cancer: a phase II feasibility study conducted by the Hellenic Cooperative Oncology Group.

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Source

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Abstract

OBJECTIVES:

To consider the safety profile and therapeutic value of the combination of estramustine and mitoxantrone in a bimonthly schedule to treat hormone-refractory prostate cancer. The survival of patients with prostate cancer who relapse after androgen ablation is limited and the therapeutic options are restricted.

METHODS:

Twenty-nine patients with relapse after previous treatment were included in the study; however, 3 patients who refused to start treatment were not included in the analysis, leaving 26 eligible patients. The median age was 64 years (range 44 to 82), the World Health Organization performance status ranged from 1 to 3, and the mean prostate-specific antigen level was 103 ng/mL (range 1 to 620). The Gleason score ranged from 2 to 9. The patients received a total of 208 therapeutic cycles (mean 8, range 3 to 24). Every cycle consisted of oral estramustine 140 mg, 3 times a day continuously, and intravenous mitoxantrone 20 mg (total dose). The regimen was repeated every 2 weeks.

RESULTS:

Twenty-seven percent of patients with measurable soft-tissue disease demonstrated an objective response, which included one complete and six partial responses. Thirteen patients (50%) had a greater than 50% reduction in serum prostate-specific antigen level. The median duration of response was 9.2 months, and the median survival for all patients was 15 months. The most common side effects were neutropenia and thrombocytopenia.

CONCLUSIONS:

The combination of estramustine and mitoxantrone is safe, well tolerated, and relatively active in patients with hormone-refractory prostate cancer. More patients are needed to partake in Phase III studies to establish the survival benefit that this combination may offer.