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


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Abstract

OBJECTIVES:
To evaluate the safety profile and therapeutic value of the combination of estramustine, mitoxantrone, and vinorelbine in the treatment of hormone-refractory prostate cancer.

METHODS:
Fifty-two patients with hormone-refractory prostate cancer were included in the study. Median age was 70 years (range, 49 to 100 years), World Health Organization performance status ranged from 0 to 2. The treatment schedule consisted of estramustine capsules (140 mg 3 times daily on days 1 to 3 and days 8 to 10 per os), intravenous mitoxantrone (12 mg/m² on day 2), and intravenous vinorelbine (25 mg/m² on day 2 and day 9), given in a 3-week cycle.

RESULTS:
Thirty-one percent of patients with measurable soft-tissue disease demonstrated an objective response, which included six complete and ten partial responses in all involved organs (bone responses not included). Twenty-nine patients (56%) had a greater than 50% reduction in serum prostate-specific antigen level. The median duration of response was 6.9 months, and the median survival for all patients was 14.5 months.

CONCLUSIONS:
The combination of estramustine, vinorelbine, and mitoxantrone is safe, well tolerated, and relatively active in patients with hormone-refractory prostate cancer.