
Vinorelbine-based chemotherapy in hormone-refractory prostate cancer.


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Abstract

BACKGROUND: No consensus exists regarding further therapy for the management of hormone-refractory prostate cancer. In this phase II study, the combination of Vinorelbine with 5-Fluorouracil and folinic acid (FLN regimen) was evaluated in patients with progressive or resistant disease after hormone therapy.

PATIENTS AND METHODS: Thirty-four patients were treated with Vinorelbine at a dose of 20 mg/m2 intravenously (i.v.) on days 1 and 3, folinic acid (FA), 100 mg/m2 i.v. and 5-Fluorouracil (5-FU), 350 mg/m2 i.v. as a short infusion on days 1 to 3. The therapy was given in an out-patient setting, every 3 weeks.

RESULTS: All of the 34 eligible patients were evaluable for toxicity and 30 for activity. A total of 127 cycles was administered (91% at full dose). Among the 155 patients with measurable disease, four had a partial response (26.6%; C.I. 95%, 28.3% to 65.7%) and four achieved stable disease. In 14 patients (47%) a clinical benefit was documented. Six out of 15 patients with bone-only involvement had stable disease (40%). The median duration of stabilization and partial response was 16 weeks (range 4-24 weeks). The most common toxicity was hematological: Grade 4 (NCI-CTC scale) in five patients at re-cycle. Other toxicities were of low incidence and easy to manage.

CONCLUSION: The encouraging results obtained with the FLN regimen in terms of clinical benefit and its predictable and manageable toxicity support the palliative role of this chemotherapeutic strategy in hormone-refractory prostate patients.

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