Vinorelbine in androgen-independent metastatic prostatic carcinoma--a phase II study


The purpose of this study was to evaluate the efficacy of vinorelbine treatment in terms of prostate-specific antigen (PSA) response and clinical benefit (decrease of pain or analgesic score for the subgroup of patients with pain), as well as its toxicity in patients with progressive metastatic androgen-independent prostatic carcinoma. 44 patients with prostatic carcinoma progressing after orchiectomy or during treatment with hormonal agents were treated with vinorelbine at a dose of 30 mg/m\(^2\) intravenously (i.v.) on days 1 and 8 of a 21-day cycle. Inclusion criteria were metastatic progressive prostatic carcinoma with prostate-specific antigen (PSA) serum levels \(\geq 3 \times\) upper limit of normal, World Health Organization (WHO) performance status \(\leq 2\), age under 85 years and adequate bone marrow, liver and renal functions. Treatment was continued until progression or a maximum of 12 cycles. Treatment was delayed for a week if haematological toxicity grade \(\geq 2\) was observed on the day of scheduled vinorelbine administration. 9 patients received less than three cycles, 6 due to rapid tumour progression. Treatment at day 1 had to be delayed in 13.7% of 183 cycles. Treatment at day 8 had to be omitted in 19.7% of all cycles. Grade \(\geq 3\) granulocytopenia occurred in 18% of patients. 4 patients had severe constipation. In 7 patients (15.9%, Confidence Interval (CI) 6.6-30.1%), a PSA response (\(\geq 50\%\) reduction of PSA levels) was observed. Among 8 patients with measurable disease, 3 had partial remission and 1 no change. Median time to PSA progression in 43 assessable patients was 11.9 weeks (range 3-52 weeks). Median duration of PSA response was 14 weeks (9-30 weeks). Clinical benefit was seen in 7 of 31 cases (23%) with baseline pain, there was no association with PSA response. Vinorelbine is a fairly well tolerated drug with a moderate single agent activity in patients with androgen-refractory prostate cancer.

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