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Phase II study of docetaxel-vinorelbine in platinum-resistant, paclitaxel-pretreated ovarian cancer.

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Source

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Abstract

BACKGROUND:

This multicenter, prospective phase II study evaluated the safety and efficacy of the combination of docetaxel and vinorelbine in patients with platinum-resistant, paclitaxel-pretreated recurrent ovarian cancer.

PATIENTS AND METHODS:

Treatment consisted of vinorelbine 25 mg/m(2) as a 20-min i.v. infusion (days 1 and 8), and docetaxel 70 mg/m(2), as a 1-h i.v. infusion (day 8). Granulocyte colony-stimulating factor support was administered prophylactically on days 12-16. Treatment was repeated every 21 days.

RESULTS:

Forty-six patients were enrolled. The median number of previous chemotherapeutic regimens was one (range 1-3) with a median treatment-free interval of 4.3 months. Four chemotherapy cycles per patient were administered. Almost 75% of the planned doses for both drugs were given. Forty-one patients are evaluable for response. Three patients (6.5% of all patients; 7.3% of evaluable patients) achieved complete response and eight (17.4% and 19.5%, respectively) a partial response to chemotherapy, leading to overall response rates of 23.9% and 26.8%, respectively. Another 34.8% (39.0%) had stable disease. At a median follow-up of 30 months, the median disease-free survival was 13 months, relapse-free survival was 5 months, time to progression was 4.5 months, and overall survival was 9.3 months. Severe toxicities included leukopenia (31%), neutropenia (35%) and febrile neutropenia (20%).

CONCLUSIONS:

The combination of docetaxel/vinorelbine is an effective regimen with manageable toxicity for the treatment of platinum-resistant, paclitaxel-pretreated ovarian cancer.