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Docetaxel in combination with dacarbazine in patients with advanced melanoma.

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Abstract

OBJECTIVES:

The number of agents that are active in patients with metastatic melanoma is limited and cure is not a realistic objective for treatment at this stage. The aim of the study was to evaluate the efficacy and safety of new combination regimen cosisting of docetaxel and dacarbazine (DTIC), as first-line chemotherapy, in patients with advanced melanoma.

PATIENTS AND METHODS:

Patients with advanced melanoma (including cerebral metastases) were eligible. Docetaxel 80 mg/m(2), i.v. over 1 h infusion on day 1, and DTIC 400 mg/m(2), i.v. over 45 min on days 1 and 2, were given every 21 days, for six cycles. All patients were premedicated, prior to each course, with methylprednisolone per os.

RESULTS:

Forty-one patients entered the study. Thirty-nine were assessable for response and 40 for toxicity. Objective responses were seen in 10 patients (24% of the eligible; 95% CI = 12.4-40.3%, 26% of the assessable and 28% of patients with cerebral metastases were excluded). Three of them achieved a complete response (7%; 95% CI = 1.5-19.9) and 7 a partial response (17%; 95% CI = 7.1-32.0), while 8 patients demonstrated stabilization of their disease (20%; 95% CI = 8.8-34.9). After a median follow-up of 20 months, the median time to progression was 7 months (range 0.5-22) and the median survival was 10 months (1-24+). The main toxicity (G3-4) was neutropenia which occurred in 8/40 (20%) patients. Additional patients had reversible G3-4 toxicities including alopecia, nausea and vomiting and fatigue; 3 of them presented mild to moderate hypersensitivity reactions to docetaxel. No toxic death was noted.

CONCLUSIONS:

The combination of docetaxel and DTIC is active and well tolerated in patients with advanced melanoma. While this combination is at least as effective as various combination regimens, it does not differ from that reported for single-agent DTIC.