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Weekly paclitaxel as first-line chemotherapy and trastuzumab in patients with advanced breast cancer. A Hellenic Cooperative Oncology Group phase II study.

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Source

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Abstract

AIM:

To evaluate the activity and acute toxicity of the combination of weekly paclitaxel as first-line chemotherapy and trastuzumab, in patients with HER-2/neu overexpressing advanced breast cancer (ABC).

BACKGROUND:

Weekly paclitaxel has been shown to be a well tolerated treatment with considerable activity in patients with ABC. Clinical trials with transtuzumab, a humanized anti-p185 HER-2/neu monoclonal antibody have demonstrated that this agent produces objective responses in patients with ABC.

PATIENTS AND METHODS:

From December 1998 to April 2000, 34 patients with HER-2/neu overexpressing ABC were treated with weekly paclitaxel; given by one-hour infusion at a dose of 90 mg/m2 immediately followed by trastuzumab, 4 mg/kg as a loading dose and 2 mg/kg i.v. given over 30 min, thereafter weekly for at least 12 weeks. Expression of HER-2/neu was determined by immunohistochemical analysis on fixed, paraffin-embedded tissues. Eligible patients were required to have > or = 25% stained tumor cells.

RESULTS:

Thirty-three patients completed at least 12 weeks of combined treatment. After completion of the 12th week of treatment, four patients (12%) achieved complete and 17 (50%) partial response. Median duration of response was 11.6 months. More frequent side effects included anemia (56%). neutropenia (27%), peripheral neuropathy (78%), diarrhea (30%), alopecia (70%), arthralgias/myalgias (62%), fatigue (59%) and hypersensitivity reactions (62%). Median time to progression was nine months while median survival had not been reached

CONCLUSIONS:

The combination of weekly paclitaxel and trastuzumab is a safe and active regimen for patients with HER-2/neu overexpressing ABC. Randomized phase III studies with this combination are warranted.