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First-line chemotherapy with paclitaxel by three-hour infusion and carboplatin in advanced breast cancer (final report): a phase II study conducted by the Hellenic Cooperative Oncology Group.

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Abstract

PURPOSE:

To evaluate the activity and toxicity of the combination of paclitaxel given by three-hour infusion, and carboplatin as first-line chemotherapy in patients with advanced breast cancer (ABC).

BACKGROUND:

Paclitaxel is an active agent in ABC. Furthermore, our group has shown that the combination of paclitaxel and carboplatin is effective in anthracycline-resistant ABC.

PATIENTS AND METHODS:

From January 1996 until March 1997, 66 women with ABC were treated with paclitaxel (175 mg/m2) by three-hour infusion followed by carboplatin at an AUC of 6 mg x min/ml every three weeks. The median age of the patients was 56 years (range 28-75). A total of 39 patients had received adjuvant chemotherapy and 22 of them were treated with an anthracycline or mitoxantrone-containing regimen.

RESULTS:

A total of 324 cycles (median: six) were administered, 273 (85%) of them at full dose. The median number of delivered cycles was six. The median delivered dose intensity (DI) of paclitaxel was 55.1 mg/m2/week (range 30.5-69.3) and the relative DI was 0.95 (range 0.5-1.2). Eight patients (12%, 95% confidence interval (CI): 5%-22%) achieved complete and 28 (42%, 95% CI: 30%-55%) partial responses. Grade 3-4 toxicities included anemia (5%), granulocytopenia (24%), thrombocytopenia, nausea/vomiting and allergic reaction (3% each), myalgias/arthralgias and neurotoxicity (1.5% each). Febrile neutropenia occurred in eight (12%) patients. Alopecia was universal. After a median follow-up of 17.3 (range 0.07-24.5) months, 48 (72%) patients have demonstrated tumor progression and 24 (36%) have died. Median time to progression was 8.6 (range 0.07-23+) months and median survival 20.4 (range 0.07-24.5+) months.

CONCLUSIONS:

The combination of paclitaxel and carboplatin has moderate activity in ABC and can be easily delivered on an outpatient basis with manageable toxicity. This regimen may be useful especially in patients to whom anthracyclines or cisplatin administration is precluded because of other concomitant diseases.