Paclitaxel and gemcitabine, as first-line chemotherapy, combined with trastuzumab in patients with advanced breast cancer: a phase II study conducted by the Hellenic Cooperative Oncology Group (HeCOG).

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Source

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Abstract

PURPOSE:

Advanced breast cancer (ABC) is an incurable disease. Standard first-line treatment for patients with HER-2/neu overexpressing tumors includes the combination of the humanized monoclonal antibody trastuzumab with chemotherapy, mainly paclitaxel. This combination is the first to demonstrate a survival advantage in this group of patients. To improve on these results, we investigated a triplet, paclitaxel-gemcitabine-trastuzumab (TGH), in a phase II study.

PATIENTS AND METHODS:

Patients with ABC were accrued to the study. Treatment consisted of paclitaxel 80 mg/m2/week, gemcitabine 1000 mg/m2 every 2 weeks, and trastuzumab 4 mg/kg loading dose and then 2 mg/kg/week. Patients were treated on study for a total of 12 weeks. Response evaluation was performed at the end of the 12 weeks. Continuation of treatment beyond the 12 weeks was left to the discretion of the investigator. Primary study endpoint was response. Toxicity assessment and survival were secondary endpoints.

RESULTS:

Between November 2000 and May 2002, 40 patients were accrued and 32 patients completed all 12 weeks of therapy. One patient died of septic shock during therapy. Grade III and IV neutropenia was seen in 12.5% of cases each. Grade III anemia was seen in two patients, and grade III and IV thrombocytopenia in three and two patients, respectively. Both paclitaxel and gemcitabine were delivered at 86% of the planned dose intensity. Six patients achieved a complete response (CR) and 15 a partial response for an overall response rate of 52.5%. An additional 25% demonstrated stable disease and 20% progressive disease. Median duration of response was 14 months. All six patients who achieved CR are still in CR for 6 to 19 months. After a median follow up of 12.2 months, 19 patients have progressed and 7 have died. Median time to progression is 13.7 months, whereas median survival has not been reached.

CONCLUSION:

TGH is a well-tolerated and effective regimen for the first-line treatment of ABC. Randomized comparison between paclitaxel, trastuzumab, and triplets are warranted.