

Paclitaxel and gemcitabine vs. paclitaxel and pegylated liposomal doxorubicin in advanced non-nasopharyngeal head and neck cancer. An efficacy and cost analysis randomized study conducted by the Hellenic Cooperative Oncology Group.

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Abstract

BACKGROUND:

The prognosis of patients with recurrent and/or metastatic head and neck cancer (HNC) is poor. Median survival of these patients following chemotherapy is in the range of 6 to 9 months. In the present randomized phase III trial we compared two new combinations containing new drugs with proven activity in phase II studies with patients with HNC.

PATIENTS AND METHODS:

From November 1999 until November 2004, 166 eligible patients with HNC were enrolled in the study. They were treated with paclitaxel 175 mg/m² on day 1 and gemcitabine 1000 mg/m² on days 1 and 8 every 3 weeks (group A, 85 patients) or with paclitaxel, as in group A, and pegylated liposomal doxorubicin 40 mg/m² on day 1 every 4 weeks (group B, 81 patients).

RESULTS:

There was no significant difference in response rate (20% versus 29%, $P = 0.21$), time to disease progression (median; 4.4 months versus 6.0 months, $P = 0.09$) and survival (median; 8.6 months versus 11.05 months, $P = 0.25$). Both regimens were generally well tolerated. The most frequently reported side effect, apart from alopecia, was neutropenia. Overall, there was no significant difference in severe toxicity between the two treatment arms.

CONCLUSIONS:

The present study could not demonstrate a survival benefit with either regimen. Both treatments were well tolerated. Randomized studies comparing each of the two regimens with standard chemotherapy are warranted.