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Paclitaxel and gemcitabine in advanced non-nasopharyngeal head and neck cancer: a phase II study conducted by the Hellenic Cooperative Oncology Group.

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Source

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Abstract

BACKGROUND:

Paclitaxel as monotherapy or in combination with other drugs has demonstrated significant activity in patients with squamous cell carcinoma of the head and neck region (SCCHN). Preclinical studies have shown gemcitabine to be highly active in SCCHN cell lines.

PURPOSE OF THE STUDY:

To evaluate the activity and toxicity of the combination of paclitaxel by three-hour infusion and gemcitabine as first-line chemotherapy in patients with recurrent and/or metastatic head and neck cancer (HNC).

PATIENTS AND METHODS:

From September 1996 until May 1998, 44 patients with non-nasopharyngeal recurrent and/or metastatic HNC entered the study. There were 37 men and seven women with a median age of 61 years (range 35-79) and a median performance status of 1 (range 0-2). The location of the primary tumor in the majority of them was either the larynx or the oral cavity. Treatment consisted of six cycles of gemcitabine 1100 mg/m2 over 30 min on days 1 and 8 immediately followed on day 1 by paclitaxel 200 mg/m2 by three-hour infusion. The treatment was repeated every three weeks.

RESULTS:

Twenty-four (55%) patients completed all six cycles of treatment. A total of 205 cycles were administered, 165 (81%) of them at full dose. The median relative dose intensity (DI) of gemcitabine was 0.93 and of paclitaxel 0.95. Except for alopecia, which was universal, grade 3-4 toxicities included neutropenia (21%), thrombocytopenia (5%), anemia (5%), infection (5%), flu-like syndrome (5%) and peripheral neuropathy (2%). Five (11%) patients achieved complete and 13 (30%) partial responses, for an overall response rate of 41%. After a median follow-up of 13 months, the median time to progression was four months and median survival nine months.

CONCLUSIONS:

The combination of paclitaxel and gemcitabine is active and well tolerated in patients with recurrent and/or metastatic HNC-randomized studies comparing this combination with other regimens are warranted.