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Paclitaxel, cisplatin, leucovorin, and continuous infusion fluorouracil followed by concomitant chemoradiotherapy for locally advanced squamous cell carcinoma of the head and neck: a Hellenic Cooperative Oncology Group Phase II Study.

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Source

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Abstract

The primary objective of this phase II study was to access the complete response (CR) rate to a new innovative induction regimen in patients with locally advanced head and neck cancer (LA-HNC). From October 2000 until October 2003 a total of 38 eligible patients (33 men and 5 women) entered the study. The large majority of them presented with a performance status of 0-1 and with clinical stage IV disease. Treatment consisted of three cycles of induction chemotherapy (IC) with paclitaxel 175 mg/m2 in a 3-h infusion on d 1, leucovorin (LV) 200 mg/m2 over 20 min immediately followed by FU 400 mg/m2 bolus and then 600 mg/m2 as a 24-h continuous infusion on d 1 and 2 and a cisplatin 75 mg/m2 over 1-h infusion on d 2 every 3 wk. This was then followed by radiation (70 Gy) and weekly cisplatin 40 mg/m2. After the completion of IC, 6/38 (16%) patients had CR. The CR rate was increased to 66% post-concomitant chemoradiotherapy (CCRT). Neutropenia (37.5%), pain (62%), nausea/vomiting (21%), and alopecia (79%) were the most frequent side effects during IC. The most pronounced toxicities during chemoradiotherapy were stomatitis (62.5%) and xerostomia (53%). Median time to progression was 11.0 mo and median survival 16.7 mo. One- and 2-yr survival rates were 73% and 38%, respectively. In conclusion, this novel induction regimen is active, is well tolerated, and can be successfully followed by CCRT with weekly cisplatin. CCRT should remain standard treatment for patients with LA-HNC. Novel induction combinations, such as that reported in the present study, should be evaluated in combination with CCRT only in the context of clinical trials.