

Concomitant radiochemotherapy vs radiotherapy alone in patients with head and neck cancer: a Hellenic Cooperative Oncology Group Phase III Study.

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Source

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Abstract

The primary objective of the present randomized phase III trial was to compare the 3-yr survival rate of patients treated with standard fractionated radiotherapy (RT) alone or with the same RT concomitantly with cisplatin (DDP) or carboplatin (Cb). From January 1995 until July 1999, 124 patients with histologically proven locally advanced non-nasopharyngeal head and neck cancer (HNC) were randomized to receive either RT monotherapy (70 Gy, Group A) or the same RT concomitantly with DDP (100 mg/m² on d 2, 22, 42, Group B) or Cb (7 AUC on d 2, 22, 42, Group C). There were no significant differences in complete response rates between patients treated with RT alone or combined chemoradiotherapy. However, median time to progression (TTP) and overall survival (OS) were significantly longer in patients treated with concomitant chemoradiotherapy. Thus, median TTP was 6.3, 45.2, and 17.7 mo in groups A, B, and C respectively ($p = 0.0002$). Similarly, median OS was 12.2, 48.6, and 24.5 mo, respectively ($p = 0.0003$). At 3 yr follow-up, 17.5% of patients in group A were alive compared to 52% in group B and 42% in group C ($p < 0.001$). Patients treated with concomitant chemoradiotherapy experienced more frequently severe hematological toxicity. Also, severe nausea/vomiting was more pronounced in group B, as expected. The present study clearly demonstrated that concomitant chemoradiotherapy with platinum analogs significantly prolongs 3-yr survival and median OS in patients with locally advanced HNC compared to conventional RT alone.