

Radiotherapy alone or with concomitant daily low-dose carboplatin in locally advanced, unresectable head and neck cancer: definitive results of a phase III study with a follow-up period of up to ten years

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ABSTRACT

Aim and background. Radiotherapy is the conventional treatment for locally advanced inoperable head and neck squamous cell carcinoma. However, the poor therapeutic results justify the development of radiochemotherapy combinations. In an attempt to improve local control and survival in patients with stage III and IV unresectable head and neck squamous cell carcinoma and based on the results of our previous dose escalation study, we undertook a prospective multicentric randomized trial.

Materials and methods. From November 1992 through December 1995, a total of 164 patients were randomized to receive radiotherapy alone (arm I) or combined (arm II) with daily low-dose carboplatin.

Results. The 3, 5 and 10-year local-regional recurrence-free survival rates were better in arm II (21.7%, 15.1% and 15.1%, respectively) than in arm I (15%, 10.7% and 10.7%), but without statistical significance ($P = 0.11$). The 3, 5 and 10-year disease-free survival rates showed the same positive trend for arm II (16%, 6.8% and 6.8% vs 9%, 5.5% and 5.5%, in arm I, respectively), again without statistical significance ($P = 0.09$). Instead, a statistical advantage was found in overall survival rates at 3, 5 and 10-years (28.9%, 9% and 5.5% in arm II and 11.1%, 6.9% and 6.9% in arm I, respectively) ($P = 0.02$). The 3, 5 and 10-year local-regional recurrence-free survival rates in stage IV disease were statistically better in arm II (21.5%, 15.9% and 15.9%) than in arm I (12.8%, 7.7% and 7.7%, respectively) ($P = 0.04$).

Conclusions. Long-term results in both treatment arms of the trial appear less positive than most published series. However, our findings do not exclude that carboplatin may be beneficial, but the benefit in local control must be lower than the 15% assumed to dimension the trial. **Free full text available at www.tumorionline.it**

Key words: chemotherapy, multicentric trial, squamous cell carcinoma, survival.

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