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Comparison of sequential and simultaneous chemo-radiotherapy for advanced hypopharyngeal carcinoma - Results of a randomized study

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In prospective randomized study, a comparison was drawn between intensified sequential chemo-therapy (arm A) and simultaneous chemo-radiotherapy (arm B) in stage IV hypopharyngeal cancer. G-CSF support was given in both arms; chemotherapy consisted of 2 courses of CDDP (25 mg/m²/d for 5 days) and 5-FU (750 mg/m²/d for 5 days continuously). Radiotherapy dosages were 70 Gy on the primary lesion and 60 Gy on the neck. Ninety eight patients were randomized; 60 patients (28 arm A, 32 arm B) finally fulfilled inclusion criteria. Complete remission could be observed in 49% in arm A and in 57% in arm B (p=0.07) and the two-year survival was 27% and 47%, respectively.

Key words: hypopharyngeal neoplasms-drug therapy; radiotherapy; treatment outcome

Material and methods

In this single center study, 98 subsequent unselected patients with advanced, non-resectable squamous cell carcinomas of the hypopharynx (UICC stage IV) were randomized to two different therapeutic regimes: sequential chemo-radiotherapy (arm A) or simultaneous chemo-radiotherapy (arm B).

The patients in arm A received two courses of CDDP (dosage 25 mg/m²/d for 5 days) and 5-Fluorouracil (dosage 750 mg/m²/d for 5 days as continuous infusion), followed by the application of G-CSF for 6 days. Course 2 was started already at day 14 to intensify chemotherapy and was followed by external beam radiotherapy (70 Gy on primary lesion, 60 Gy on neck).

Arm B consisted of concomitant chemo-radiotherapy with identical dosages of chemotherapeutic agents, but with 3-week interval between the 2 courses.

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Results

After a thorough examination, approximately one third of the patients were not eligible or could not be enrolled mainly because of medical problems, such as renal failure or liver cirrhosis. Finally, 28 patients were treated in arm A and 32 patients in arm B.

Sequential treatment was better tolerated due to less mucositis (WHO grade 3 mucositis 4% in arm A, versus 32% in arm B and 73% of the patients could receive the second course in time. Neutropenia was more often and more distinctive in arm B. Three therapy-related deaths occurred.

Complete remissions (according to the WHO definition) could be achieved in 49 % in arm A and in 57 % in arm B (Logrank-Test: p = 0,07). Long lasting complete remissions were seen in both arms. The two-year overall survival was 27% in arm A and 47 % in arm B (Figure 1).

Discussion and conclusions

Escalation of chemotherapy with G-CSF support demonstrated to be feasible in both groups. As expected, acute toxicity in arm B was pronounced.

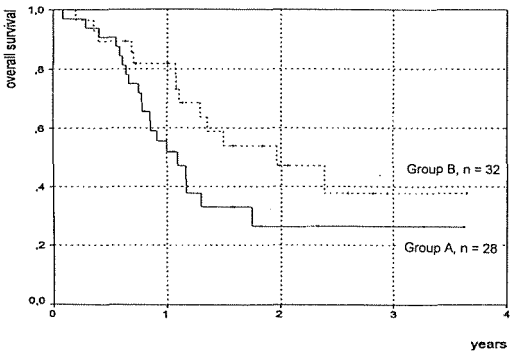

Figure 1. Overall survival of patients treated by sequential (Group A) and simulateous chemoradiotherapy (Group B).

This study suggests that concomitant chemo-radiotherapy in comparison with intensified sequential chemo-radiotherapy is even more beneficial.

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