

1 Long-Term Follow-Up of the RTOG 9501/Intergroup Phase III Trial: Postoperative Concurrent Radiation Therapy and Chemotherapy in High-Risk Squamous Cell Carcinoma of the Head and Neck

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Purpose/Objectives: Previous analysis of this Intergroup trial demonstrated that with a median follow-up among surviving patients of 45.9 months, the concurrent postoperative administration of cisplatin and radiation therapy improved local-regional control and disease-free survival of patients who had high-risk resectable head and neck carcinomas. With a minimum of 10 years of follow-up potentially now available for all patients, these results are herein updated to examine long-term outcomes. **Material/Methods:** 410 analyzable patients who had high-risk resected head and neck cancers were prospectively randomized to receive either radiation therapy (RT: 60 Gy in 6 weeks) or identical RT plus cisplatin, 100 mg/m² i.v. on days 1, 22, and 43 (RT + CT). **Results:** At 10 years, the local-regional failure rates were 28.8% vs. 22.3% (p=0.10), disease-free survival was 19.1% vs. 20.1% (p=0.25) and overall survival was 27.0% vs. 29.1% (p=0.31) for patients treated by RT vs. RT + CT respectively. In the unplanned subset analysis limited to patients who had microscopically involved resection margins and/or extracapsular spread of disease, local-regional failure occurred in 33.1% vs. 21.0% (p=0.02), disease-free survival was 12.3% vs. 18.4% (p=0.05) and overall survival was 19.6% vs. 27.1% (p=0.07) respectively. Cause-specific survival trended towards improved outcome with RT + CT for patients whose death was due to the study cancer; however, more deaths not due to the study cancer were observed in patients treated with concurrent cisplatin. **Conclusion:** At a median follow-up of 9.4 years for surviving patients no significant differences in outcome were observed in the analysis of all randomized, eligible patients. Analysis of the subgroup of patients who had either microscopically involved resection margins and/or extracapsular spread of disease showed improved local-regional control with concurrent administration of chemotherapy. The subgroup of patients who were enrolled only because they had tumor in multiple lymph nodes did not benefit from RT + CT.

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