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Phase III Comparison of Prophylactic Cranial Irradiation Versus Observation in Patients With Locally Advanced Non-Small-Cell Lung Cancer: Primary Analysis of Radiation Therapy Oncology Group Study RTOG 0214.

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Abstract

PURPOSE This study was conducted to determine if prophylactic cranial irradiation (PCI) improves survival in locally advanced non-small-cell lung cancer (LA-NSCLC). **PATIENTS AND METHODS** Patients with stage III NSCLC without disease progression after treatment with surgery and/or radiation therapy (RT) with or without chemotherapy were eligible. Participants were stratified by stage (IIIA v IIIB), histology (nonsquamous v squamous), and therapy (surgery v none) and were randomly assigned to PCI or observation. PCI was delivered to 30 Gy in 15 fractions. The primary end point of the study was overall survival (OS). Secondary end points were disease-free survival (DFS), neurocognitive function (NCF), and quality of life (QoL). Kaplan-Meier and log-rank analyses were used for OS and DFS. The incidence of brain metastasis (BM) was evaluated with the logistic regression model. **Results** Overall, 356 patients were accrued of the targeted 1,058. The study was closed early because of slow accrual; 340 of the 356 patients were eligible. The 1-year OS ($P = .86$; 75.6% v 76.9% for PCI v observation) and 1-year DFS ($P = .11$; 56.4% v 51.2% for PCI v observation) were not significantly different. The hazard ratio for observation versus PCI was 1.03 (95% CI, 0.77 to 1.36). The 1-year rates of BM were significantly different ($P = .004$; 7.7% v 18.0% for PCI v observation). Patients in the observation arm were 2.52 times more likely to develop BM than those in the PCI arm (unadjusted odds ratio, 2.52; 95% CI, 1.32 to 4.80). **CONCLUSION** In patients with stage III disease without progression of disease after therapy, PCI decreased the rate of BM but did not improve OS or DFS.

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