Conclusion: Our results suggest that postoperative adjuvant treatment with oral UFT (250 mg/m^2/day) significantly improves in survival in patients with pathological stage I adenocarcinoma of the lung, especially those with stage IB disease (T2N0M0).

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A phase II trial of chemoradiotherapy followed by surgery in pancoast tumors: initial report of the Japan Clinical Oncology Group trial (JCOG 9806).

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Background: Although preoperative radiotherapy (Rx) has long been the standard treatment for Pancoast tumors, or superior sulcus tumors (SST), both the complete resection rate and long-term survival remain poor. SWOG reported favorable results when using preoperative chemoradiotherapy (CxRx) to treat SST (JTCS 2001). Objectives: To evaluate the safety and efficacy of a trimodality approach for the treatment of SST. The primary endpoint was the 3-year survival rate. Patients: Pathologically documented M0 NSCLC with at least invasion to the first rib. Patients with N2 disease were excluded, however, patients demonstrating involvement of the ipsilateral supraclavicular node (SCN) without any mediastinal node metastasis were included.

Methods: Two cycles of MVP chemotherapy (Cx) were given q 4weeks; mitomycin C 8mg/m2 on day 1, vindesine 3mg/m2 on days 1 and 8, and cisplatin 80mg/m2 on day 1. Rx for the tumor and ipsilateral SCN was started on day 2 of each Cx cycle. The total irradiated dose was 45Gy/25 fr comprising 27Gy/15fr with the first Cx and 18Gy/10fr with the second Cx. If the tumor was resectable, then the patients (pts) underwent a thoracotomy 2-4 weeks after the completion of the induction CxRx. Those with unresectable disease received an additional Rx booster.

Results: From May/99 to Nov./02, 76 pts were entered into the study. Median age; 57.5 (range 34-74), M/F; 67/9. Clinical stages were T3/T4 64/12, N0/1/3 64/9/3. PS 0/1 30/46, >5% weight loss in 17% of the pts. Histology; Ad/Sq/Others 34/27/15. As of Feb./03, 71 pts were reported to be off treatment. Induction CxRx was completed in 94% of the pts. Fifty-four pts (77%) underwent a surgical resection and 49 pts (69%) received a pathologically complete resection. A pathologic downstaging was achieved in 22 (31%), of whom 11 pathologically demonstrated CR (no residual viable tumor). Major postoperative morbidity was reported in 8 pts, which includes chylothorax, empyema (2), pneumonitis (2), hemorrhage and ARDS (2). There were 3 treatment-related deaths; 1 from post operative ARDS, 1 from postoperative hemorrhaging and 1 from septic shock during CxRx. The one-year survival rate was 77% (95%CI:66-87%), and the one-year progression-free survival rate was 65% (95%CI:54-77%).

Conclusions: These results reproduced those of the SWOG study in terms of resectability, safety and short-term survival. The effectiveness of this trimodality approach was thus suggested. All pts will have completed the therapeutic regimen by Aug./03.

1080 ORAL

Induction chemotherapy followed by concurrent RSR13 (Efaproxiral) and trt for patients with locally advanced NSCLC: mature results of a phase II study and comparison with the results from RTOG 94-10.

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Purpose: To compare survival results between RTOG 94-10 and Study RT-010, Phase 2 study of induction chemotherapy followed by concurrent RSR13 (efaproxiral) and thoracic radiation therapy (TRT).

Methods: RSR13 is a synthetic allosteric modifier of hemoglobin that reduces hemoglobin oxygen-binding affinity, facilitates oxygen release, and increases tissue pO_2. RSR13 has been studied as a radiation sensitizer for patients with locally advanced Stage IIIA-B NSCLC in a Phase 2 study (RT-010). Patients received induction chemotherapy [paclitaxel (225 mg/m^2) and carboplatin (AUC=6) on days 1 and 22 (2 cycles)] followed by TRT (64 Gy/32 fractions/starting on day 43-50) with concurrent daily infusion of RSR13 (50-100 mg/kg). RTOG 94-10 was a Phase 3 study in Stage II-III NSCLC patients. Here we compare survival results from RT-010 (N = 49 pts; minimum potential follow-up = 28 months) to both the RTOG 94-10 sequential chemoradiotherapy arm (S-CRT; N = 201 pts) and the concurrent chemoradiotherapy arm (C-CRT; N = 201 pts).

Results: Demographic characteristics were comparable among all groups; however, a higher percentage of RT-010 patients (85%) had KPS of 90-100 than S-CRT (77%) or C-CRT (75%) patients. Also, a higher percentage of RT-010 patients (53%) had Stage IIIA disease than S-CRT (41%) or C-CRT patients (43%). The median survival times (MST) for all patients in the RT-010 study and the S-CRT and C-CRT arms are 20.6, 14.6, and 17.0 months, respectively. A matched-case analysis was performed whereby patients in the 3 groups were matched by stage and KPS (exactly) and age (±5 yrs). MST for the matched-case patients in the RT-010 study and the S-CRT and C-CRT arms are 20.6, 15.1, and 17.9 months, respectively. A stratified Cox model indicated a slight improvement in survival favoring RT-010 over both the S-CRT (hazard ratio = 0.87) and C-CRT arms (hazard ratio = 0.76).

Conclusion: Although the sample size of the RSR13 study is too small to identify statistically significant differences in survival, these results suggest that RSR13 added to S-CRT may have a favorable impact on survival comparable to C-CRT. A randomized, Phase 3 trial of S-CRT±RSR13 for NSCLC is ongoing.

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Stereotactic radiotherapy of primary lung cancer. Results of a phase II trial

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Background: Stereotactic radiotherapy is now used for treatment of tumours outside the brain. However, the evidence for this treatment is sparse.

Material and methods: Twenty-six patients with primary non-small-cell lung cancer were treated with stereotactic radiotherapy. All patients had stage T1-2,N0,M0 disease and were technically operable, but inoperable due to severe chronic obstructive lung disease or other co-morbidity. Patients were equally divided between between males and females. Median age was 69 (47-79) years. Patients were either immobilised by use of the Stereotactic Body Frame (Elekta) or by a custom made whole body fixation system. Stereotactic radiotherapy was given by use of 5-8 MLC-shaped fields with a central dose of 45 Gy in 3 fractions over 5-8 days. The CTV was encompassed by the 95% and the PTV by the 66% isodose curve. Margin between CTV and PTV was at least 5 mm in the transversal and 10 mm in the cranio-caudal plane. Evaluation of toxicity by the WHO toxicity scale was performed at baseline and 14 days, 56 days and every 3 months after treatment, and CT-scans were performed every 3 months after treatment. Median follow-up time was 12 (5-42) months.

Results: Local control was observed in more than 80% of the patients. Distant progression was observed in eight of the cases. Median time to progression was 10 months. Fifty percent of the patients were without progression and 65% were surviving at 18 months after treatment. Significant worsening of performance status and lung function was observed at 14 days and 6 months after treatment compared to baseline.

Conclusions: This study shows high local control probability and moderate toxicity after stereotactic radiotherapy of primary lung cancer.

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Can we optimize timing of initial follow-up after radiotherapy from study of patterns of first failure? - Evidence from patients with NSCLC

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Increasing attention is being paid to evaluating the effectiveness of follow-up (FU) after cancer treatment. An important aim of regular surveillance is to detect events associated with treatment failure (recurrence, toxicity), which