Conclusions: Cisplatin, Etoposide and CPT-11 triplet is a well tolerated regimen with evidence of exceptional activity in patients with advanced SCLC. It thus warrants further clinical exploration in phase II.

808 POSTER

Early recognition of local relapse of lung cancer by follow-up of tumor marker CYFRA 21-1 level

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Background: Lung carcinoma is a polygenic disease. Early recognition of lung cancer in an early stage of disease as well as relapse provides an appropriate treatment. Tumor marker CYFRA 21-1 is a prognostic and predictive factor in non-small cell lung cancer (NSCLC) that contributes to earlier treatment. The aim is to contribute to earlier recognition of relapse of primary lung cancer by continous follow-up of patients with purpose of increase of efficiency of the clinical diagnostics.

Material and Methods: The study includes 882 patients with diagnosed lung cancer who were controled for therapy efficiency. Serum CYFRA 21-1 has been measured by ECLIA method before therapy and twelve times after the therapy through the period of 60 months. Measurements were performed along with the clinical methods in order to compare the results.

Results: The sensitivity of CYFRA 21-1 before therapy was 78,88% in 516 squamous cell carcinoma (SQC) patients and 70,77% in 366 adenocarcinoma (AD) patients, which contributed to diagnosis of NSCLC and justified the use of CYFRA 21-1 in clinical praxis. The sensitivity was 96,74% in SQC patients with relapse and 91,56% in AD patients with relapse.The sensitivity raises from stage IA to IIIA in both SQC and AD. The efficiency of therapy was evaluated using the first two measurements after applied therapy. Both median and Wilcoxon test proved significant differences between stages of disease in both histological types (p

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CT-guided stereotactic radiation therapy for stage I non-small cell lung cancers.

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SRT is highly effective for brain metastases from NSCLC. As such, we started CT-guided SRT for primary lesions of stage I NSCLC 9 years before. Between 1994 and 1999, initial 50 patients were treated. Of these 21 were medically inoperable and 29 refused surgery. In most patients, SRT was 50-60 Gy in 5-10 fractions for 1-2 weeks. 18 patients also received conventional RT of 40-60 Gy before SRT. A median follow-up period of living patients was over 5 years: range 45-90 months. The 5-year overall survival was 58% in all 50 patients and 72% in 29 patients who refused surgery. No definite adverse effects were observed except for 2 patients with minor bone fracture and 6 with temporary pleural pain. CT-guided SRT was highly safe and effective for stage I NSCLC. Additional studies should be warranted to confirm the efficacy of this new treatment.

810 POSTER

The influence of radiotherapy on lung function in patients with non-small cell lung cancer.

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Background: Radiotherapy may cause irreversible damage of normal lung tissue. However, only little is known about the relation between absorbed dose, irradiated volume and lung function.

Material: In a period from 1995 to 2002 218 patients with non-small cell lung cancer (NSCLC) were treated with curative intended radiotherapy. The distribution of disease-stage was: Twenty-six stage I, 25 stage II, 151 stage III, and 16 patients with recurrent disease after primary surgery. Radiotherapy was given with involved-field technique. Total dose to the planning target volume was 60 to 80 Gy. In 8 patients curative treatment were not accomplished. Lung function parameters in the shape FEV-1 and FVC were performed before treatment and every 3 month in the follow-up period.

Results: The changes in mean FEV-1 and FVC in percent of the initial value in time is demonstrated in the figure. At 48 months the mean FEV-1 was 85% (95% CI: 73-97%) and the mean FVC was 95% (95%CI: 85-105%) of the initial value.

Conclusion: Patients with NSCLC often have a compromised lung function. Curative intended radiotherapy may furthermore result in a moderate decrease in lung function parameters, especially FEV-1. This must be considered in each patient before final treatment decision.

811 POSTER

Adjuvant therapy with gefitinib ('Iressa', ZD1839) following complete resection in Japanese patients with non-small-cell lung cancer: safety report of the first 38 patients recruited

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Objective: A randomized, double-blind, placebo-controlled, Phase III multicenter trial to compare survival between adjuvant therapy with gefitinib 250 mg/day and placebo for patients (pts) with completely resected non-small-cell lung cancer (NSCLC).

Methods: Pts with completely resected NSCLC (IB, IIA, IIB or IIIA), within 4-6 weeks following surgery, were randomized to receive either 250 mg/day gefitinib or matching placebo for 2 years, until recurrence/secondary carcinoma or withdrawal criteria were met. Enrollment began in August 2002, and the planned accrual was 670 pts over 2 years.

Results: As of October 2002, 38 pts had been randomized into this trial*; 18 received gefitinib (M/F, 14/4) and 20 received placebo (M/F, 15/5). The demography of enrolled pts was well balanced between the two arms in terms of sex, performance status, and histology type and disease stage. The most common drug-related adverse events (AEs) were CTC grade 1/2 gastrointestinal and skin disorders, observed in 66.7% and 88.9% of pts who received gefitinib, and 25.0% and 30.0% who received placebo, respectively. Grade 3 drug-related AEs (liver function disorders, pneumonitis, eczema, and neutropenia) were seen in 22.2% of pts in the gefitinib arm and 5.0% in the placebo arm. The drop out rates were quite high in both arms with only 4/18 pts in the gefitinib arm and 12/20 in the placebo arm continuing treatment as of March 2003. Interstitial lung disease (ILD) was reported in 3 pts, 1 pt in the gefitinib arm died (they had taken concomitant medication of other ILD inducing drugs), and 2 pts in the placebo arm. There was no impact on surgery-related complication or wound healing between the two arms.

Conclusion: There were no unexpected AEs seen in an adjuvant setting compared with those reported in Phase II trials (IDEAL 1 and 2) of more advanced NSCLC pts (Fukuoka et al. JCO 2003; in press; Kris et al. Proc ASCO 2002; 21:292a). There was no impact on surgical-related complication when dosing gefitinib within 4-6 weeks after operation. Poor compliance in this trial may indicate that dose/schedule modification may be required in the adjuvant setting in Japan.

*The recruitment was stopped in October 2002 and the trial was finally terminated in March 2003 due to the difficulty in recruiting patients in Japan in the current environment, and poor compliance with dosing schedule.

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