Median observation time of all pts alive 17 months (6–46) (mts). MST in RO-res pts: 32 mts; 14/47 NED/RO-res pts have relapsed so far (5 CNS, 2 liver, 2 bone, 1 pumonal (hematogen), 4 local). 29 Pts who could not be operated: Treatment not completed (medical reasons) 7, PD during CTx ± RTx 7; CTx/RTx refused 4; OP refused 2; irresectable after CTx/RTx 9. *Toxicity:* CTx: leucopenia 3° 32% 4° 8%, thrombocytopenia 3° 17% 4° 11%; infections 3°/4° 4%, 2 early deaths due to septicemia; CTx/RTx: leucopenia 3° 38% 4° 9%, thrombocytopenia 3° 18% 4° 5%, infections 3°/4° 3%, esophagitis 3° 41% 4° 4%; Perioperative: 4 postoperative deaths (1 card. failure, 2 stump insuff, 1 pleural empyema). *Conclusions:* This intensive preoperative treatment program is tolerable and highly effective for these unfavourable prognostic subgroups of LAD NSCLC patients.

1066 POSTER

SURGICAL MANAGEMENT OF NON SMALL CELL LUNG CANCER WITH INVASION OF THE CHEST WALL

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The chest wall is involved by direct lung tumour extension in approximately 2–8% of the patients. Between 1976 and 1989, 1365 patients underwent resection of non small cell lung cancer and this study is concerned with 73 of these patients (5.3%) who required resection of an area of the chest wall including one or more ribs because of direct tumour invasion (T3).

The overall 5-year survival rate was 31.5% (23 patients); 17 (74%) were N0, 5 (21.7%) were N1 and only 1 (4.3%) was N2.

Our experience confirms earlier reports: stage IIIA patients T3N0M0 have a better 5-year survival rate than N1 and N2, indicating a potentially radical tumour excision even in this stage.

1067 POSTER

DNA CONTENT IN CORRELATION WITH POSTSURGICAL STAGE IN NON-SMALL CELL LUNG CANCER

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The relationship between DNA content and TNM stage, histology, histological differentiation, survival as well as recurrence was assessed in a study of 215 patients with non-small cell lung cancer (NSCLC) who had undergone complete resection (R0).

Cellular DNA content was obtained by image cytometry on paraffin-embedded-tumor tissue and by flow cytometry on tumor cell suspension. DNA aneuploidy was measured in 179 (83%) out of the 215 NSCLC. The aneuploid/diploid ratio were identical in TNM stage, histology and grading. Only in adenosquamous carcionomas the proportion of DNA aneuploid tumors was significantly higher. Aneuploid tumors showed higher recurrence rates (23.2%) during follow-up as diploid tumors (11%). Survival analysis showed that life expectancy of patients with diploid tumors was longer than those with aneuploid carcinomas (5-year survival rate of 69% vs. 49%). The most significant difference was found in patients with adenocarcinoma (5-year survival rate of 100% for diploid tumors vs. 45% for aneuploid tumors).

These results suggest that DNA aneuploidy may provide an independent prognostic factor for patients with NSCLC.

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1068 POSTER

CISPLATIN 120 MG/M^2 VS. CARBOPLATIN 500 MG/M^2 IN COMBINATION WITH MITOMYCIN C AND VINDESIN; A RANDOMIZED PHASE III STUDY IN 164 PATIENTS WITH STAGE IIIB AND IV SQUAMOUS-CELL BRONHOGENIC CARCINOMA

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A randomized phase III study of Cisplatin vs. Carboplatin in 1:4 ration in patients with stage IIIb and IV squamous cell bronhogenic carcinoma, in combination with Mitomycin C and Vindesin was performed in 164 patients. The study is still open and accrual of new patients is planed to be stopped by July 1995. The arm A received Cisplatin 120 mg/m^2, Mitomycin C 8 mg/m^2 and Vindesine 3 mg/m^2. The arm B received Carboplatin 500 mg/m^2 with the same dosage of Mitomycin C and Vindesine per cycle. Chemotherapy was applied until signs of progressive disease, 6 cycles at most. Both arms were well balanced regarding age, sex, clinical stage, histological grade and performance status. 84 patients were randomized to the Cisplatin group (83 evaluable for activity) and 80 to the Carboplatin group (76 evaluable for activity). In the Cisplatin group there were 2.41% CR, 30.12% PR, 43.37% SD, 24.10% PD, RR 32.53%, mean time to progression 4.21 ± 3.09 months, median 3.43; mean overall survival 6.72 ± 3.69 months, median 6. In the Carboplatin group there were 5.26 CR, 30.26% PR, 43.24% SD, 21.05% PD, RR 35.72%; mean time to progression 5.01 ± 3.27 months, median 4.40; mean overall survival 7.65 ± 5.26 months, median 6. The Carboplatin arm displayed a higher incidence of grade III/IV hematological toxicity, while the Cisplatin regimen was more emetogenic and nephrotoxic. Carboplatin substituting Cisplatin in the regimen seems to be associated with a similar activity and a longer interval to progression not affecting the overall survival.

1069 POSTER

A STUDY ON THE RELATIONSHIP BETWEEN P53 MUTATION AND SMOKING CIGARETTES FOR HUMAN NON SMALL CELL LUNG CANCER

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Recently, to explore the relationship between p53 mutation and smoking cigarettes for human non small cell lung cancer (NSCLC), during the period from 1993 to 1994, the p53 mutation of 52 patients with pathologically proven NSCLC was assessed. In this group, male 43, female 9, the ratio of male to female is 4.8:1. Age incidence from 30 to 71 year-old, median age is 55. The histopathologic categories of 52 cases consisted of 30 patients with squamous cell lung cancer and 22 patients with adenocarcinoma of the lung. ABC technique of immunohistochemistry was used for detecting accumulation of p53 protein of all resected NSCLC specimens. Of them, a mutated allele of one case with adenocarcinoma on bases of detection of p53 mutation with PCR-SSCP analysis was isolated and reamplified. Nucleotide sequence analysis was detected, the result revealed that 280 code AGA has been replaced by ACA. In 25 patients with p53 mutation, the smoking individuals accounted only for 17 cases (68%). In 27 patients without p53 mutation, the smoking individuals accounted for 20 cases (74%). No significant difference was found in both groups statistically ($P > 0.05$). The positive rate of p53 mutation of smoker in the squamous cell carcinoma and adenocarcinoma was 45.5% and 46.6% respectively, there were no significant differences ($P > 0.05$) between the squamous cancer and adenocarcinoma. The results revealed that p53 gene mutation might not be closely related with smoking cigarettes.

1070 POSTER

PHASE II TRIAL WITH DOCETAXEL IN PATIENTS (PTS) WITH NON SMALL CELL LUNG CANCER (NSCLC)

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This study proposes to evaluate Docetaxel's activity in pts with advanced and/or metastatic NSCLC. Pts eligibility included no prior therapy measurable disease, Karnofsky performance status ≥60, adequate bone marrow, hepatic, and renal function and a signed informed consent. Treatment (Rx) consisted of Docetaxel 100 mg/m^2 given by IV infusion over one hour every three weeks with Dexamethasone 8 mg PO BID × 5 days starting the day prior to Rx and Diphenhydramine 50 mg IV 30 min. prior to Rx to prevent hypersensitivity reactions. Of the 45 pts entered, 38 have been completed Rx. All are eligible and 32 were evaluable. Of the 6 non evaluable pts, 3 had serious adverse effects, 2 an increase in symptoms and one never got treated. A total of 146 Rx were given. Toxic events included mild to severe hypersensitivity reaction and febrile and non febrile neutropenia. Two deaths were related to febrile neutropenia. One complete and 8 Partial responses were observed in 32 pts (28%). In conclusion, these preliminary results indicate that Docetaxel will probably be an active agent in the treatment of NSCLC.

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