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A PHASE II STUDY OF CISPLATIN (P)AND LOW DOSE CONTINUOUS ORAL ETOPOSIDE (V) IN ADVANCED NON SMALL CELL LUNG CANCER (NSCLC)

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Between December 1990 and October 1992, we entered 39 patients (p) with advanced NSCLC on a Phase IItrial of P and low dose continuous oral V. Patients eligible were: Advanced stage disease (metastatic except those with central nervous system met. and stage IIIb with positive pleural effusion), age lower than 76, Karnofsky index greater than 60%, Creatinine clearance greater than 50 ml/min and no previous chemotherapy treatment. Treatment schedule was: P 100mg/m2 on day 1 and V 50 mg/m2/d for 21 consecutive days every 28 days. The next course was administered when the granulocite count was ≥ 3000/mm3 and platelet ≥ 100000. 32 men and 7 women were treated. Median age, 52 years(r:21-73) Median Karnofsky index, 80%. 36p were stage IV and 3 IIIb with pleural effusion. 37 p are evaluable for toxicity and response. 109 courses were given, (median number 2, range:1-6). Hemetologic toxicity grade 3 or 4 was: Grade 3 anemia in 5p, grade 3 trombopenia in 3p, grade 3 neutropenia in 15p and grade 4 in 9 p (1 toxic death due to pneumonia and sepsis). Alopecia was almost universal and nausea and vomiting were common but manageable. The Response rate was 11/37 partial responses and no complete responses with an overall response rate of 29.7% (IC 17-44%). No significant diferences in response rate were observed by sex, performance status or weight loss. Median survival was 6 months for the overall group. So, this dose and schedule of oral V combined with P seems to be active in advanced NSCLC with aceptable toxicity, but it does not appear to offer any advantage over the 3-5 days schedule of etoposide.

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ACTUAL INDICATIONS TO ENDOSCOPIC LASER-THERAPY IN THE LUNG CANCER NON-SMALL CELL.

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More than half of the lung cancers,non-small cell,can't be resected and the research of the best palliative treatment is actual.When the tumor is not resectable,is central and involving a main or a lobar bronchus and has an important intraluminal component,the andoscopic laser-therapy,looking at evaporation of the tumor and at reopening of the bronchus,has today a correct indication.From March 1987 to January 1993 306 patients have been treated,1089 applications in all.We have observed no complication related to laser,a reopening of bronchi,with a significant radiological modification in 75% of cases and on an average the period for bronchial reopening is of 4 months.I think that ,in specified cases,as before remembered,laser therapy give good results.

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TREATMENT AND RESPONSE OF SUPERIOR VENA CAVA SYNDROME DUE TO MALIGNANT TUMOURS.

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Superior vena cava syndrome is commonly due to malignant tumors often incurable. In the present study we reviewed the response rate and survival of such syndrome after treatment with radiotherapy and/or chemotherapy. Material 18 patients were included and evaluated. Male 16 female 2. Performance status >60%. Median age 57(37-81). Histologically were 9 small cell lung cancers, 8 non-small cell lung cancer,1 thymoma.
Treatment. 12 patients were initially treated with radiotherapy (Rt) (5 SCLC, 6 NSCLC, one thymoma)and 6 with chemotherapy (4 SCLC and 2 NSCLC). Chemotherapy was Cis-platinum based combination.
Response. Of 12 patients with Rt, 8 responded (66%), 3 of 5 SCLC, 5 of 6 NSCLC. 6 of 6 patients with chemotherapy responded (100%).One patient with thymoma did not responde to Rt and responded to chemotherapy. Response was considered objective reduction of measurable tumour and also reduction of superior vena cava signs. Median survival was 9 months (3-20+).
Conclusion: Chemotherapy may be equally effective as initial treatment of superior vena cava syndrome due to small cell lung cancer, non-small cell lung cancer and thymoma as radiotherapy, if not superior.

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TREATMENT OF NON-SMALL CELL LUNG CANCER (NSCLC) STAGE IIIb-IV WITH IFOSFAMIDE (IF), 4EPIDOXORUBICIN (EPI) AND MITOMYCIN C (MMC). PRELIMINARY REPORT.

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From March 1991 to February 1993, 72 patients (pts) with stage IIIb-IV NSCLC and non prior treatment were randomized to receive combination chemotherapy as follows: Arm A: IF 2500 mg/m2 IV, day 1 and 2; Mesna 20% of IF dose IV at hour 0, 3, 6 and 9; EPI 70 mg/m2 IV day 1 and MMC 6 mg/m2 IV, day 1. Arm B: the same schedule as in arm A, but without MMC. Cycles were repeated every four weeks. 34 pts were evaluated in arm A and 33 pts in arm B. In arm A, 14 pts achieved (41%) objective response (CR 4, PR 10); arm B: 14 pts achieved (42.4%) objective response (CR 0, PR 14). Progressive disease was seen in 11 pts (arm A), and in 8 pts (arm B). Median time remission is about 9.5 months (mo) for arm A, and about 8+ mo for arm B. Median survival time for responders is 11 mo for arm A and 10 mo for arm B. Toxicity ranged from mild to moderate (OMS II-III). IF + EPI seems to be a useful combination for NSCLC. The inclusion of MMC did not improve response and survival.

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PHASE II TRIAL WITH WEEKLY CISPLATIN (CDDP) AND CONTINOUSLY ORAL ETOPOSIDE (VP-16) IN ADVANCED NON-SMALL CELL LUNG CANCER (NSCLC).

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We performed a phase II trial with VP-16 50 mg/m^2/day po day 1-21 q28 and CDDP 35 mg/m^2 iv day 1,8 and 15 q28. Forty three untreated patients (pts)(38 male/5 female) with histologically proven and inoperable NSCLC were included. All pts had evaluable disease by CT scan. Median age was 57 years (range: 33-70). Stage IIIA 4 pts, stage IIIB 18 pts and stage IV 21 pts. Histology was squamous 22 pts, adenocarcinoma 17 pts and large cell/poorly differentiated 4 pts. Performance status WHO 0-1, 32 pts and WHO 2, 11 pts. 3 pts were not evaluable for response (2 death of intercurrent disease, 1 lost follow-up). A median of 3 cycles was given (range 1-8). The response rate was 50% (20/40) (95% CI: 35%-65%) with 3 pts achieving complete response (7.5%). On stage IV overall response rate was 45% (9/20)(95% CI: 24%-66%). Severe toxicity (WHO 3-4) included leukopenia 16% of all pts, anemia 9%, diarrhea 10%, mucositis 14%. Nausea/vomiting grade 1-2 in 40%. Alopecia grade 2-3 was common (90%). We conclude that this ambulatory regimen was well tolerated and achieved a promising response rate. A phase III study is warranted.

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PHASE II STUDY OF TOPOTECAN IN PATIENTS WITH NON-SMALL CELL LUNG CANCER.

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Topotecan is a hydrosoluble semisynthetic analogue of camptothecin undergoing extensive clinical evaluation. A Phase II clinical trial of Topotecan in patients with metastatic non-small cell lung cancer previously untreated is in progress. Topotecan is administered i.v. as a 30 min daily infusion for 5 consecutive days at a dose of 1.5 mg/m^2/day. Twenty one patients have been entered into the study. Fifteen patients are evaluable for response and toxicity. Characteristics of evaluable patients are as follows: histology: adenocarcinoma 7, squamous cell carcinoma 3, poorly differentiated carcinoma 4, bronchioalveolar carcinoma 1; performance status: 0, 3 patients, 1, 12 patients. Two patients (13.3%) have achieved a partial remission (50% reduction in measurable disease for ≥4 weeks), 3 patients (20%) a minor reponse, 3 patients have remained stable, and 7 patients have shown progressive disease. From a total of 52 courses given, grade 3 or 4 toxicity has been limited to myelosuppression (predominantly granulocytopenia) lasting <7 days in most patients; two epidoses of neutropenic fever requiring hospitalization have been recorded. Other toxicities include alopecia in most patients and grade 1 or 2 nausea and vomiting in about 50% of patients. Although preliminary, these results indicate that Topotecan has moderate activity in non-small cell lung cancer and is easily tolerated. Accrual will continue up to 40 evaluable patients.