RT in 8 patients who completed the planned treatment (C. Gridelli, Lung Cancer 2000); the Maximum Tolerated Dose (MTD) was 5 mg/m^2/day.
Oral vinorelbine (NVBo) has produced similar results in advanced NSCLC when compared to IV NVB. Based on the bioavailability of NVBo (40%) and the available marketed dosages (20−30 mg), a feasibility study has been implemented in patients (pts) with locally advanced or inoperable stage III NSCLC.
Material and Methods: Three to 6 pts between 18 and 70 years, with histologically proven untreated locally advanced inoperable stage IIIAN2/IIIB (supraclavicular lymph nodes and pleural effusion excluded) NSCLC, adequate bone marrow, hepatic and renal function, KPS $\geqslant$ 80%, were expected at each dose level. Eight levels were planned with NVBo given concomitantly with 60 Gy RT (2 Gy/day; 5 days a week) from 20 mg total dose up to 60 mg total dose on days (D) 1, 3 and 5 each week during 6 weeks. Here we report the analysis of the first 5 dose levels.
Results: Between 06/02 and 07/06, 12 men and 3 women were enrolled with stages IIIA N2 (2 pts) or IIIB (13 pts). Median age 61.2 years [49.3−71.3], median KPS 100% [80–100%]. The first 5 levels were completed without the occurrence of dose-limiting toxicity (3 pts per dose level). Overall, 11 pts received 100% of the planned NVBo dose during the 6 weeks treatment period and 4 pts missed only one intake for other reason than toxicity.
Neither grade $\geqslant$3 haematological/ non-haematological toxicity nor treatment interruption >2 weeks occured. Only 2 pts experienced grade 2 radiation-induced oesophagitis and constipation. Objective response was observed in 4 pts (27%) and 2 additional pts had confirmed partial response during follow-up.
Conclusion: NVBo with this new original schedule of 3 times a week intake concomitantly with RT for 6 weeks, is still well tolerated with dosages up to 50 mg on D1, 40 mg D3 and 40 mg D5, each week, without MTD. Additional dose escalation is ongoing to determine the recommended dose for phase II trials.

6583 POSTER

The prognostic value of hemoglobin concentration and WBC count in sequential radio-chemotherapy or radiotherapy alone for locally advanced non-small cell lung cancer

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Background: The aim of this study was to evaluate the prognostic value of hemoglobin concentration at the beginning (Hb1) and at the end (Hb2) of sequential radio-chemotherapy or radiotherapy alone for lung cancer. The analysis accounted for WBC count, platelets count, as well as tumor and treatment related variables.
Material and Methods: The retrospective study included 224 patients treated between 1998 and 2003 for stage IIIB non-small cell lung cancer: 118 patients received cisplatine-based induction chemotherapy (2−6 cycles) followed by conventionally fractionated 3-D conformal radiotherapy (median total dose 66 Gy, dose per fraction 2.0 Gy), while 106 patients were treated with radiotherapy alone (median dose 66 Gy). The variables used in the analysis included Hb, WBC and platelets counts at the beginning and at the end of radiotherapy, as well as 8 tumor and treatment related variables (general performance status, age, sex, TN stage, number of chemotherapy cycles, total radiation dose, overall radiation treatment time). A multivariate Cox proportional hazard regression analysis was performed to identify the variables that significantly affected overall survival (OS). Backward stepwise regression was used to optimize the model.
Results: Several of the parameters studied (e.g. platelets count, $p = 0.02$) appeared to have a significant influence on OS of 224 patients when univariate model was used, but only Hb2 remained significant ($p < 0.00001$) in a multivariate model. Likewise, only Hb2 appeared significant ($p = 0.00004$) when multivariate analysis was restricted to subgroup of the patients treated with radiotherapy alone. By contrast, not only low Hb2, but also the above-average WBC count at the end of radiotherapy (WBC2), low number of chemotherapy courses, and advanced N stage appeared as significant and independent predictor of impaired OS among the patients treated with radio-chemotherapy.
Conclusion: Hemoglobin concentration at the end of radiation treatment appear to be the strongest predictor of long-term survival among the patients with non-small cell lung cancer treated with radiotherapy alone. In patients treated with induction chemotherapy the above-average WBC count at the end of radiotherapy was also a predictor of an impaired survival. This may suggest that the above-average WBC2 may be considered as one of the surrogate markers of individual resistance to cytotoxic therapy, and/or a sign of a deficient systemic treatment.

6584 POSTER

Induction chemotherapy with vinorelbine and a platinum compound followed by concurrent chemoradiotherapy and consolidation chemotherapy with the same drugs for stage III non-small-cell lung cancer (NSCLC) – a phase II study

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Purpose: to determine the response rate (RR), toxicity, time to progression (TTP) and survival (S) of induction Chemotherapy (ChT) with Vinorelbine (Vrb) and Cisplatin (Cis) or Carboplatin (Carbo) followed by concurrent chemoradiotherapy (ChRT) and consolidation ChT with the same drugs, for stage III NSCLC.
Methods and Materials: 53 patients (pts) were included from 05.02.2004 to 20.12.2006: median age 57(39–73), M/F=50/3, PS 1/2=31/22, stage IIIA/IIIB=6/47, squamous cell cc 43, large cell cc 5, adenocc 1, "non-small" carcinoma 4. Treatment consisted of 2 cycles (c) of induction ChT with Vrb (25 mg/sqm, d1, 8, q21) and Cis (100 mg/sqm, d1, q21), or Carbo (AUC 5, d1, q21), followed by 2 more c (with reduced doses: Vrb 15 mg/sqm, d1, 8, q21, Cis 80 mg/sqm, d1, q21 or Carbo AUC 2.5, d1, q21) given concurrently with RT and 2 c of consolidation ChT with the same drugs. RT (15MV) has been administrated to a total dose of 60−68 Gy/30−34 fractions. The last 17 pts benefited of conformal-3DRT. 86% of pts completed at least 4 c, 70% completed 5 or 6 c of ChT. The optimal doses of RT have been received by 75% of pts.
Results: 53 pts were evaluable for toxicity. Severe grade (gr) 3 or 4 neutropenia occured in 5 pts, anemia in 4.One pt had gr 3 trombocitopenia and also 2 pts had gr 3 gastro-intestinal toxicity. Gr 3 neuropathy occured in 1 pt.
Two pts stopped treatment after 2 c of induction ChT (one because of gr 3 neuropathy, gr 2 febrile neutropenia and evolution of the disease, and the other because of gr 4 neutropenia and decompensation of diabetes melitus). Other 2 pts didn't receive cycle 3 of chemotherapy because of toxicities or evolution of the disease. Of the 53 pts. evaluable after induction ChT, 5.7% obtained CR, 37.8% PR, 52.8% had SD and 3.7% PD. Of the 49 pts evaluable for response after ChRT, 33% achieved CR, 37% PR for an overall RR of 70% (CI:58−82), 18% of pts had SD, and 12% had PD.
Progression-free-S at 1 year was 38% (CI:24−53%) with a mTTP of 9 months (CI:6.9−17.9). The disease specific S at 1 year was 60% (CI:44%-73%) and the mS was not reached yet. For the 27 pts still alive the median follow-up was 9.6 months.
Conclusions: Preliminary results indicate that induction ChT followed by concurrent ChRT with Vrb and a Platinum compound, followed by consolidation ChT with the same drugs given for advanced stage III NSCLC is feasible, well tolerated and has a positive effect on the RR and survival

6585 POSTER

Accelerated radical radiotherapy for non-small cell lung cancer (NSCLC) using two common regimens: a single centre audit of outcome

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Background: Radical radiotherapy (RT) regimens for NSCLC vary considerably. Our centre uses both continuous hyperfractionated accelerated radiotherapy (CHART) and accelerated hypofractionated RT using 55 Gy in 20 fractions over 4 weeks. This audit reports outcome according to RT regimen.
Materials and Methods: All case notes and RT records of radically treated patients between 1999 and 2004 were retrospectively reviewed. Basic patient demographics, tumours, characteristics, RT and survival data were collected. Patients treated with CHART received 54 Gy in 36 fractions over 12 days.
Results: One hundred and thirty-seven patients received CHART and 140 received hypofractionated RT. Median age was 65 (41−83) in CHART and 73 (33−87) in hypofractionated group respectively. Sixty-five percent were male in CHART compared to 61% in hypofractionated group. Histological confirmation was obtained in 90% of CHART and 76% of hypofractionated patients. For CHART patients, stages 1, 2, 3 and unclassified were 12%, 8.0%, 68% and 12% and the staging for the hypofractionated regimen was 54%, 11%, 34%, 2% respectively. WHO performance status was 0/1, 2/3 and undocumented in 88%, 6%, and 7% of CHART patients and 78%, 22%, and 0% of the hypofractionated patients. Prior chemotherapy was given in 34% CHART and 19% of hypofractionated patients. Median overall survival (OS) from time of diagnosis was 16.6 months and 21.4 months in