Conclusion: The combined radiochemotherapy was well tolerated. We obtained the same good results with a normofractionated RT with fewer side effects than studies with hyperfractionated RT. The KI and the haemoglobin level at the start of the treatment seem to be the most relevant prognostic factors.

798 POSTER

Impact of third line ZD 1839 therapy on patients with advanced non-small cell lung cancer (NSCLC) who had failed prior platinum and/or docetaxel-based regimens (Astra Zeneca Expanded Access Programme)

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Background: Patients with locally advanced or metastatic NSCLC pretreated with two or three regimens of conventional standard chemotherapy have a median overall survival time of 4 months (Massarelli et al. Lung Cancer 2003). Iressa, an EGFR tyrosine kinase inhibitor, has recently shown a favourable overall tumor growth control (30%) and symptomatic improvement (40%).

Aim: The efficacy of a third line with ZD 1839 as an outpatient salvage treatment was analyzed on the basis of tumor response rates, time to third progression (TTTP), time to death (TTD) and disease-related symptom response.

Patients and Methods: 32 patients who had failed two previous chemotherapy regimens (median age 64; M/F, 69/31%; PS 1/2/3, 50/44/6%, locally advanced/metastatic disease, 69/31%) were treated with oral ZD 1839 250 mg/daily.

Results: An early tumor progression (TTTP <3 months) occurred for a minority of evaluable patients (4/24, 17%). A favourable overall tumor growth control was observed in 20/24 (83%) of the heavily pretreated patients, including partial remissions in 2/24 (8%) (both women with histologically confirmed adenocarcinoma) and stable disease in 18/24 (75%) patients. Median overall time to third progression and TTD evaluated from the beginning of the third line treatment on 13 evaluable patients were respectively of 4 and 6 months. Approximately 80% of patients (13/16) having a time to second progression not lower than 4 months with Docetaxel, had a TTTP with Iressa greater than 4 months. The majority of drug-related adverse events were mild and reversible. Grade 2/3 diarrhoea and skin rash required treatment's discontinuation in only 2 patients (8%). Performance status (Karnofsky Scale) scores decreased in 10/32 patients (31%), allowing to reduce the analgesic use.

Conclusion: Our experience confirms Iressa's activity and acceptable toxicity. A significant correlation was seen regarding second line treatment with Docetaxel and related time to progression. An updated efficacy and toxicity analysis will be presented at the meeting.

799 POSTER

Randomized trial of docetaxel plus cisplatin (DC)versus etoposide plus cisplatin (EC) in locally advanced, recurrent, or metastatic non-small cell lung cancer (NSCLC).

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Background: The aim of this study was to compare DC and EC regimens in terms of response rate, safety profile, and overall survival (OS).

Materials and Methods: From April 2000 to March 2002, 78 patients with locally advanced (LA, Stage IIIB), recurrent (R), or metastatic (M) NSCLC were recruited. Eligibility criteria included: age ≥ 18 years, pathologically confirmed NSCLC, no prior chemotherapy, Karnofsky performance score (KPS) ≥80%, measurable disease, no brain or leptomeningeal metastasis, and signed informed consent.

Patients:

	DC	EC
n	40	38
Median Age (years)	64.5	59.0
Adeno./ Squamous	47.5%/50%	50%/48.7%
LA/ M/ Local R	50%/47.5%/2.5%	42.1%/57.9%/0%
Prior RT/ Surgery (n)	1 /2	0/ 4
KPS	80	80

DC treatment consisted of 75mg/m^2 of both agents given on day 1, every 3 weeks for 6 cycles. EC treatment consisted of 75 mg/m^2 of cisplatin on day 1, and 100mg/m^2 of etoposide on days 1–3, every 3 weeks for 6 cycles.

Results: Thirty-four patients from the DC arm and 33 patients from the EC arm were included in the efficacy analysis. Two patients in the DC arm did not receive treatment; 1 patient withdrew consent and 1 developed brain metastasis. Four patients from the DC arm received the first cycle of treatment but could not be evaluated for response; 1 patient was lost to follow up (f/u), 2 withdrew consent, and 1 died as a result of an accidental fall. From the EC arm, 3 patients withdrew consent, 1 was lost to f/u, and 1 died of cardiac arrhythmias. Adverse events NCI grade ≥ 3 occurred in 32 patients (19 DC/13 EC): neutropenia 4(10.5%)/6(15.8%); febrile neutropenia 3(7.9%)/0; sepsis 1(2.6%)/0; infection 1(2.6%)/0; nausea 2(5.3%)/4(10.5%); diarrhea 2(5.3%)/1(2.6%); fatigue 3(7.9%)/0, alopecia 6(15.8%)/6(15.8%).

Conclusion: DC offers superior response rates over EC and shows a trend in improved median survival in chemotherapy-naïve patients with locally advanced (Stage IIIB), recurrent, or metastatic NSCLC. There was no significant difference in TTP between groups and both regimens were well tolerated.

800 POSTER

The placental growth factor (PlGF) gene is more highly expressed in small cell lung cancers compared to non-small cell lung cancers

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Background: The characteristics of SCLC are that they disseminate in their early stages to distant organs, and that they recur frequently despite initial high sensitivity to chemotherapy and radiation. Differences in the gene expression profiles in small cell lung cancers (SCLC) and non-small cell lung cancers (NSCLC) may explain their different clinical characteristics. The aims of this study were (1) to identify genes differentially expressed in SCLC and NSCLC using mRNA differential display, and (2) to determine the clinical relevance of such genes in lung cancer.

Material and Methods: RNA differential display using three SCLC and six non-SCLC cell lines was used to identify a differentially expressed gene. Differential expression of the gene was confirmed in additional lung cancer cell lines using RT-PCR. Immunohistochemical staining for the gene product was performed on paraffin-embedded tissue from lung cancer patients. We examined the relationship between the expression of the gene and clinical parameters, including disease stage, response to treatment and survival time.

Results: The PlGF gene was identified as preferentially expressed in SCLC compared with NSCLC cell lines using mRNA differential display. Further analysis of 45 lung cancer cell lines using RT-PCR showed that the PlGF gene was expressed in nine of 13 SCLC cell lines (69%) and five of 32 NSCLC cell lines (15.6%) ($P < 0.001$, Fisher's exact test). Immunohistochemistry using anti-PlGF antibody on the paraffin blocks from lung cancer patients showed that PlGF expression was significantly higher in SCLC than NSCLC tissue sections (32% vs 5.6%, $P = 0.041$, Fisher's exact test). Expression of PlGF protein did not correlate with disease stage, response to treatment or survival time in SCLC patients.

Conclusion: The present study suggests there is higher expression of PlGF in SCLC compared to NSCLC. It may be that higher expression of the angiogenic factor PlGF contributes to differences between the progression of SCLC and NSCLC, especially in regard to the nature of SCLC metastasis.

801 POSTER

Oral chemotherapy and upper gastro-intestinal tolerance (UGT) improvement of nausea and vomiting in non-small-cell-lung-cancer (NSCLC) patients (pts) treated with oral navelbine (NVB) and standard antiemetic prophylaxis

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Background: UGT during oral chemotherapy is a constraint which may limit its use in cancer pts. Oral NVB is a new formulation that allows a