Results: 91 patients (48 males, 43 females) were evaluable. Median age was 66 yrs. 70% had PS of 0 or 1, 27% PS 2, and 3% PS 3. The total number of courses recorded was 170 (107 carboplatin and vinorelbine, 42 cisplatin and vinorelbine, and 21 vinorelbine alone). D8 vinorelbine was not dministred as planned in 23 courses (14%). In 20 (12%) courses, d8 vinorelbine was omitted, delayed in 2, and given with dose reduction in 1. Low FBC was the reason for d8 vinorelbine omission in only 1 course; a patient with PS 2 treated with vinorelbine monotherapy.
Conclusions: D8 vinorelbine administration can generally be safely led by clinical assessment alone in patients receiving combination treatment. We will still assess FBC on d8 in patients receiving single agent vinorelbine. This will save NHS resources and improve patient comfort.

9063 POSTER

Intravenous Topotecan in patients with advanced non-small cell lung cancer pre-treated with platinum and taxanes: Results of a phase II study

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Background: Topotecan, a semi-synthetic camptothecin analogue with topoisomerase I interaction has shown to be an active agent in the treatment of advanced refractory lung cancer and ovarian cancer. In this report, experience with this drug is described when used as a single agent in patients with advanced NSCLC refractory to chemotherapy regimens containing at least platinum and taxanes.
Methods: Patients with NSCLC refractory to previous chemotherapy including planitum and taxanes in first and/or subsequent lines of treatment and KI = 60% were eligible for the study. Topotecan was given at a dose of 1.25 mg/m^2 I.V. daily for five days, repeated every 21 days until progression disease or intolerable toxicity occurred. Efficacy and toxicity were assessed following OMS criteria. The Simon two-stage design and the Kaplan-Meier method ware applied to estimate activity and progression free survival (PFS) respectively.
Results: Thirty four patients were included showing the following features: median age of 52 years (range 43−69) and karnofsky PS of 70 (50−80), 26 were male and 8 female. Twenty-one (63%) pts had adenocarcinoma, ten (25%) squamous cell and three (12%) undifferentiated carcinoma. The median number of disease sites and prior regimens received were two in both cases. After 64 cycles administered, patients received a median of 2 cycles of treatment (1−9). All patients except one were considered evaluable for toxicity, with the recording of five episodes of (15%) nausea/vomiting grade 1−2 and two (6%) of asthenia grade 1. Four (12%) patients developed anaemia grade 2−3 and neutropenia grade1. Three additional patients (9%) had neutropenia grade 2 and one (3%) grade V. Among 32 evaluable patients for activity, one (3%) showed partial response, nine (27%) stable disease and 23 (70%) progression disease. Median PFS was 52 days (12−210).
Conclusion: Intravenous topotecan at that dose and schedule of administration has little activity in terms of response rate in third line of advanced NSCLC. The role and utility of chemotherapy in this setting warrants further investigation and confirmation through comparatives studies.

9064 POSTER

Phase II study of the combination chemotherapy with weekly carboplatin and gemcitabine in advanced non-small cell lung cancer

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Background: The efficacy and safety of combination chemotherapy with weekly carboplatin (CBDCA) and gemcitabine (GEM) was evaluated as a protocol for first-line chemotherapy with advanced non-small cell lung cancer (NSCLC).
Methods: Eligible patients were the measurable NSCLC with the treatment of previously untreated patients. Patients were treated with a regimen consisting of GEM 1000 mg/m^2 and CBDCA AUC 2 on day 1 and day8 at every 3 weeks.
Results: A total of 46 patients (pts) (Male/Female, 30/16 pts; median age 67 years [27−75]; Performance Status 0/1/2, 22/21/3 pts) were enrolled. Twelve patients (26%) had initial stage III disease and 34 patients (76%) had stage IV disease. The histological subtypes were adenocarcinoma (78%) and squamous cell carcinoma (15%). Fourteen patients (30%) achieved a partial response. The median number of treatment cycles was 3 (range 1−12). The time to progressive disease was 19.4 weeks and the median survival was 46.3 weeks. The one-year survival rate was 46.9%. The major toxicity was hematotoxicity and occurred grade 3 or 4 neutropenia(58.7%), thrombocytopenia(45.7%). One patient of grade 3 general fatigue were shown, and grade 2 nausea (17.4%), rash (8.7%), fever (6.5%), vomiting (6.5%), general fatigue (6.5%), constipation (2.7%) were occurred. None of other severe toxicities were appeared.
Conclusion: Weekly chemotherapy with CBDCA plus GEM is effective and is acceptable for the first line treatment of advanced NSCLC

9065 POSTER

Myelotoxicity of oral Topotecan in relation to treatment duration: Phase I study

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Background: Topotecan intravenously administered has a place in Small Cell Lung cancer and ovarian cancer in pretreated patients. Oral Topotecan has been recently brought into clinical practice and has been suggested to be given for 5 days continuously at a dose of 2.3 mg/m^2 every 3 weeks. The published data showed a quite common myelotoxicity. The aim of the present trial is to define the daily dose and treatment duration that permits safe toxicity.
Material and Methods: Twenty eight patients were included, 25 males and 3 females. The median age was 60 years (46−77). In 26 patients the diagnosis was small cell lung cancer and in 2 patients ovarian cancer. All patients were treated before by 1 or more lines of chemotherapy. 14 patients were treated for 1−3 cycles with oral Hycamptin at a dose 2.3 mg/m^2 for 5-days, planned to be repeated every 3 weeks. In 7 patients the same dosage of Topotecan was given for 4 days. 7 patients had 3 days treatment's duration and 2 more patients were included in the 3 days duration, after unacceptable toxicity from the group of 5 or 4 days treatment.
Results: Nine patients from the 5-days treatment group presented serious myelotoxicity of Grade III and IV (64.28%). Myelotoxicity included neutropenia (Grade IV: 42.85%), thrombocytopenia of Grade II-III in 8 patients (57.14%) and anemia Grade II-III in 7 patients (50%). 4 patients treated for 4 days had neutropenia of grade III-IV (57.145) and half of those thrombocytopenia. 4 patients out of 9 with 3 days of treatment had grade III and IV neutropenia (44.4%). The grade IV neutropenia was 22.2%. Several patients had dose reduction by 25% or shortened treatment duration from 5 days to 4 days, or from 4 days to 3. Two treatment related deaths were seen in the 5-days group and one in the 4-days group. It is worth to be mentioned that nearly one-third of the patients were previously heavily treated. Granulocyte growth factor was applied in over 60% of the patients.
Conclusion: The safe duration of treatment with oral Topotecan seems to be not longer than 3-days at a dose of 2.3 mg/m^2.

9066 POSTER

Antitumour activity of pemetrexed (Pem) and carboplatin in elderly patients in IIIb and IV stages of non small cell lung cancer (NSCLC): a multicenter phase II study

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Background: Pemetrexed activity is synergistic with both carboplatin and cisplatin in chemonaive NSCLC patients. Two phase II Pem plus carboplatin trials have confirmed the doublet's activity in NSCLC and response rates were 31% and 24% (Scagliotti and al 2003, Zinner and al 2005). In elderly patients who are currently excluded from trials, age can impair physiologic processes and reduces the therapeutic index of drugs. In addition, because of renal toxicity related to cisplatin, carboplatin is a good alternative in this population suggesting a balanced benefit/risk profile when combined with Pem.
Materials and Methods: Sixty-two elderly patients ($\geqslant$ 70 years) with measurable stage IIIb not amenable to radiotherapy/IV NSCLC, without brain metastases, received at least one dose of chemotherapy. Pem 500 mg/m^2 over 10 min on day 1 with folic acid and vitamin B12 supplementation followed by carboplatin AUC 5 on the same day were given every 21 days for 6 cycles. Primary endpoint was objective response rate.

Results: 62 patients received at least one dose of chemotherapy. Median age was: 76.4 yrs [70.2−86], baseline ECOG performance status PS 0: 16.1% and PS 1: 83.9%. Stages IIIb: 21%, IV: 79%. Non squamous cell carcinoma: 66.1% (adenocarcinoma: 51.6%, large cell carcinoma: 8.1%, others: 6.5%), squamous cell carcinoma: 33.9%. The median number of administered cycles was 5. 77.4% patients received at least 3 cycles of study therapy. 49/62 patients (79.03%) had at least one tumor assessment performed after the start of treatment and were qualified for the primary outcome analysis. The objective response rate (RECIST criteria; assessed by investigators) was 28.6% (95% CI [16.58; 43.26]) all were partial responses, stable disease was 42.9%. Grade 3/4 toxicities related to study drugs were: asthenia 16.1%, anorexia 4.8%, diarrhea 3.2%, dyspnea 3.2%. Hematological grade 3/4 events were: neutropenia: 51.6%, leucopenia: 30.7%, thrombocytopenia: 29%, anemia: 19.4%. One related fatal septic shock occurred in this trial.
Conclusion: In first line NSCLC, the combination of Pem plus carboplatin could be a valuable treatment alternative in elderly patients. Neutropenia is the most frequent toxicity in this combination. Response rate is the range of data collected in younger population.

9067 POSTER

Survey of European lung cancer evaluating choice of treatment and tolerability in observed 2nd line (SELECTTION): characteristics of patients with NSCLC at time of initiating 2nd line chemotherapy – French results

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Background: There is not enough evidence on duration of 2nd line chemotherapy and reasons for discontinuation in real practice.
Materials and Methods: SELECTTION is a 12-month prospective observational study designed to assess time from treatment initiation to discontinuation, reasons for discontinuation and its impact upon patient outcomes including survival and resource utilization in patients with NSCLC treated after failure of one prior chemotherapy. 1012 patients who have received first-line chemotherapy for locally advanced or metastatic NSCLC and were initiating second-line treatment were included in the observation and followed up to 12 months in 11 countries. The present analysis reported the baseline patients' characteristics of French patients.
Results: 506 patients (476 eligible for analysis) were enrolled between January 07 and January 08 by 57 physicians, 74% pneumologists and 81% working in public setting. Patients were 61.5 ± 9.9 years old, 75% male and 90% former or current smokers. At time of initiating 2nd line chemotherapy, 83% were stage IV NSCLC, 81% non-squamous, 26% ECOG grade 2 or more. As a 1st line chemotherapy, 33% of the patients received gemcitabine + platinum, 20% vinorelbine + platinum, 20% docetaxel + platinum, 16% paclitaxel + platinum and 11% other combinations. 66% had response or stable disease and 32% had progressive disease. Median time from initial diagnosis to start of 1st line therapy was 2.0 months (min 1.0; max 93.1). The median duration of the 1st line was 12.3 weeks (min 0.1; max 151.1). The median time between end of 1st line and start of 2nd line was 4.8 weeks (min 0.0; max 51.0) for patients who progressed and 17 weeks (min 0.0, max 360.6) for patients who responded or had stable disease. The planned 2nd line was pemetrexed (56%), docetaxel + platinum (13%), erlotinib (22%) and other combinations (9%). National or hospital level guidelines drove mainly the choice of 2nd line chemotherapy. The planned duration of 2nd line was set as an exact number of cycles (44%) with a median of 3 cycles, up to disease progression (25%) or not known in advance (7%).
Conclusions: These preliminary results provide information about patients' characteristics at time of initiating 2nd line for locally advanced or metastatic NSCLC and treatment algorithms in different institutions in daily practice in France.

9068 POSTER

Analysis of experience with cisplatin or carboplatin in first line combination chemotherapy with paclitaxel for advanced and metastatic Non Small Cell Lung cancer (NSCLC)

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Background: The purpose of this study is the evaluation of single institution experience with two chemotherapy regimens containing paclitaxel and either cisplatine or carboplatine in patients with advanced or metastatic Non Small Cell Lung Cancer (NSCLC).
Patients and Methods: Between January 2004 and December 2008 we have treated 91 patients with advanced or metastatic NSCLC. Forty (40) patients received cisplatin 70 mg/m^2 + paclitaxel 175 mg/m^2 D1, and fifty one (51) patients carboplatine AUC 6 + paclitaxel 175 mg /m^2 D1 every three weeks.
Results: See the table.

Patient characteristics

	Paclitaxel + cisplatin (n = 40)	Paclitaxel + carboplatin (n = 51)
Gender		
Female	5	1
Male	35	50
Age (years)	58.72 (39−70)	63.2 (53−74)
Squamous cell carcinoma	27	28
Adenocarcinoma	12	16
Carcinoma with large cells	1	2
others	0	5
Stage		
IIIB	24	23
IV	16	28
Toxicity profile grade 3−4		
Anemia	1 (0.5%)	3 (5.8%)
Neutropenia	10 (5.5%)	1 (1.9%)
Thrombocytopenia	1 (0.5%)	8 (15.6%)
Nausea/vomiting	19 (10.4%)	8 (15.6%)
Peripheral neuropathy	5 (2.7%)	0 (0%)

In arm with paclitaxel + cisplatin, there was one complete response (2.5%), 14 (35%) partial response. Stable disease was observed in 5 (12.5%) case, and progressive disease in 20 (50%) case. In arm with paclitaxel + carboplatin, there were one complete response (1.9%), 5 (9.8%) partial responses, 9 (17.6%) stable diseases and 36 (70.5%) progressive diseases. Median survival was 9.5 months in an arm with cisplatin and 8.2 months in arm with carboplatin.
Conclusion: Chemotherapy with cisplatin is more effective in term of response and survival than chemotherapy with carboplatine in patients with advanced or metastatic NSCLC.

9069 POSTER

A risk–benefit analysis according to age using pooled data from two phase II trials of cisplatin plus S-1 for non-small-cell lung cancer in Japan

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Background: Elderly patients are less likely to tolerate chemotherapy than younger patients because of increased comorbidity and impaired organ function. Optimal treatment regimens for this patient population remain controversial. S-1 is an oral anticancer agent combining tegafur, 5-chloro-2,4-dihydroxypyridine, and potassium oxonate. The main adverse effects of this drug are hematological and gastrointestinal toxicity. To evaluate the efficacy and safety of cisplatin plus S-1 chemotherapy in patients with advanced non-small-cell lung cancer, two phase II studies were performed in Japan. To determine whether tolerance to cisplatin plus S-1 chemotherapy differs according to age, we analyzed pooled data from these two trials.
Materials and Methods: We compared the incidence of main toxic effects between elderly (aged ⩾65 years) and younger patients (aged <65 years). Grade 3 or 4 toxic effects according to the National Cancer Institute Common Toxicity Criteria that had the highest incidence (neutropenia, anemia, and anorexia) were identified. A risk–benefit analysis using time to event, defined as the time to the first occurrence of grade 3/4 toxicity (neutropenia, anemia, and anorexia), disease progression, or death, was performed.
Results: The study group comprised 110 patients with stage IIIB or IV non-small-cell lung cancer. The median age was 61 years (range, 36−74). Sixty-seven patients were younger than 65 years, while 43 were 65 years or older. The main toxic effects were neutropenia (<65 years: 14 patients [20.9%]; ⩾65 years: 14 patients [30.6%]), anemia (<65 years: 6 patients [9.0%]; ⩾65 years: 12 patients [27.9%]), and anorexia (<65 years: 11 patients [16.4%]; ⩾65 years: 7 patients [16.3%]). The time to event analysis revealed no difference between elderly and younger patients (P = 0.68).