bine treatment could be considered as an optimal option for these p. We retrospectively evaluated efficacy and toxicity of oral vinorelbine administered as single agent for first-line NSCLC treatment in elderly p.

Methods: 1 cycle was equivalent to a 3-week period. Treatment consisted of oral vinorelbine 60 mg/m^2/week during the first 3 weeks, escalating to 80 mg/m^2/week if no grade 4 or no more than two grade 3 neutropenia were observed during first cycle. At 80 mg/m^2, if grade 4 or 2 consecutive grade 3 neutropenia ocurred, the dose was reduced to 60 mg/m^2. Treatment was administered for 6 cycles, unless progression of the disease was observed earlier.

Results: Data on 46 p were collected in 11 Spanish centres. Median age was 77 years (range 70-85). Male, 87%; female, 13%. ECOG PS 0, 26.8%; 1, 68.3%; 2, 4.9%. Stage IIIA, 4.3%; IIIB, 30.4%; IV, 65.2%. Histology: scamous, 56.5%; adenocarcinoma, 28.3%. Self-sufficiency in ADL and IADL was 82.5% and 55% of the p analyzed. 81.9% of the p had comorbidities. 46 p are available for toxicity and 27 for response. Median cycles: 3 (1-8). 158 cycles were performed, 13.4% were delayed and 5.4% had dose reduction. Hematological toxicities (%p): grade 3/4 neutropenia, 8.7%/8.7%. Grade 3 non-hematological toxicities: asthenia, 6.5%; anorexia, 4.3%; respiratory, 4.3%; pain, 4.3%; nausea and vomiting, 2.2%. No grade 4 non-hematological toxicities were reported. In the evaluable p, 3 PR (11.1%) and 11 SD (40.7%) were reported (disease control 51.8%). With a median follow-up of 3.4 months (m), median survival for the whole population was 6.37 m, progression free survival 3 m.

Conclusions: This trial confirms the results of previous studies with single agent oral vinorelbine in elderly NSCLC p. It has been shown that this treatment offers a reasonable control of disease, with easy administration and a favorable toxicity profile for this specific population.

P2-287 **NSCLC: Cytotoxic Chemotherapy Posters, Tue, Sept 4**

Clinical Study of Interventional Preoperative Bronchial Arterial Infusion Chemotherapy Combining with Surgery Resection to Lung Cancer

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Background and Objective: How to improve the postoperative 5-year survival rate for lung cancer and to give more patients a chance of surgery have become research hot spots. The aim of this research is to evaluate the clinical and pathohistological responses and effects of preoperative bronchial artery infusion (BAI) chemotherapy in patients with locally advanced (stage III) non-small cell lung cancer (NSCLC).

Methods: A total of 92 cases with locally advanced NSCLC were randomly divided into two groups. BAI group received BAI chemotherapy for 2 cycles before surgical resection. Surgery group received operation only. The complete resection rate and clinical response were compared between the two groups.

Results: In the BAI group, the clinical response rate and the pathohistological response rate were 68.3% and 51.3% respectively. The complete resection rate in the BAI was 89.7%, which was significantly higher than that in the surgery group (72.5%)(P<0.05). The 1- and 2-year survival rates were 100% and 74.4% in the BAI group, and 94.1% and 60.0% in the surgery group.

Conclusion: BAI neoadjuvant chemotherapy is safe and effective, which has a good clinical and pathohistological response. It might increase the complete resection rate of the tumor of the tumor and improve the long-term survial rate of stage III NSCLC patients.

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P2-288 **NSCLC: Cytotoxic Chemotherapy Posters, Tue, Sept 4**

Retrospective comparison of adenosine triphosphate-based chemotherapy response assay (ATP-CRA)-guided chemotherapy versus empirical chemotherapy in unresectable nonsmall cell lung cancer

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Background: We previously reported the outcomes of ATP-CRA-guided platinum-based 2-drug chemotherapy for unresectable NSCLC (CANCER, in press). The study showed more favorable response and survival in chemo-sensitive subgroup than in chemo-resistant subgroup within assay-guided chemotherapy group. We retrospectively compared outcomes of assay-guided chemotherapy and empirical chemotherapy in this study.

Methods: From Sep. 2003 to Oct. 2005, we performed an in vitro chemosensitivity test, ATP-CRA. According to the assay results, platinum-based 2-drug chemotherapy was given to patients with chemo-naïve, unresectable NSCLC. At the same period, medical records of unresectable NSCLC patients receiving platinum-based empirical chemotherapy were reviewed retropectively. Prognostic variables such as performance status (PS), stage, and chemotherapy regimen were matched with the ratio of 1: 3-4. Chemotherapy response and progrerssion-free survival (PFS) were compared between the assay-guided and empirical chemotherapy groups.

Results: Eighty-two patients were enrolled. Eighteen were included in assay-guided group (AG) and 64 in empirical group (EG). Seventy (85.4%) patients had Eastern Cooperative Oncology Group (ECOG) PS of 0-1 and 12 (14.6%) had ECOG PS of 2. Stage IIIB was in 24 (29.3%) patients and stage IV in 58 (70.7%). Fifty (61.0%) patients received paclitaxel plus platinum and 32 (39.0%) received gemcitabine plus platinum. These 3 prognosticators were well matched in the determined ratio. Other variables such as age, sex, brain metastasis, and histology were not also significantly different between the 2 groups. The median cycles of admistered chemotherapy were 3 in AG and 4 in EG. (P=0.267). AG showed a trend for higher response rate (50.0% vs 37.5% in EG; P=0.339). However, the median PFS was not different between the 2 groups (4.4 months in AG vs 4.4 months in EG; P=0.624).

Conclusions: Clinical outcomes of ATP-CRA-guided platinum-based chemotherapy and empirical chemotherapy were not different in chemo-naïve, unsesectable NSCLC.

P2-289 **NSCLC: Cytotoxic Chemotherapy Posters, Tue, Sept 4**

Docetaxel with platinum as first line chemotherapy in advanced non-small cell lung cancer (NSCLC)

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Introduction: The most commonly prescribed chemotherapy in first line treatment of advanced NSCLC in UK patients (pts) is gemcitabine and carboplatin. However, for cancer centres(CC) where pts live in outlying areas, a safe, 3-weekly regimen is preferable. Docetaxel (D) was approved by NICE for first line use with cis- (Pt) or carboplatin (C) in 2005. There is no evidence that any combination has superior activity in first line use but the 'trade off' of alopecia for less frequent hospital visits was explored in our practice.

Methods: Since 2004, all pts with a confirmed diagnosis of NSCLC with advanced disease on CT staging, not suitable for a clinical trial and living >1 hour's drive from the CC are offered first line chemotherapy with D and Pt or C. Scalp cooling was offered from 2006. Data were entered on to a locally held Excel database.

Results: Between August 2004 and November 2006, 41 pts were treated. 33 were male and the age range was 47-77 (median 63) with all pts of ECOG performance status 0 or 1. The average number of cycles delivered was 4 (range 1-4). Stage of disease was IIIA (10pts), IIIB (9) and IV (22). Three pts had radiotherapy concomitantly, 19 sequentially and 2 prechemo. Response (WHO) was evaluable in 35 pts: CR 4, PR 13, NC 9 and PD 9 for an overall disease control rate of 74%. Pts who elected to have scalp cooling did not develop alopecia >grade I in 90% of cases. Tolerance was good with no grade 4 toxicity. Survival data are being updated with increased patient numbers from this ongoing protocol.

Conclusion: Docetaxel with platinum is a safe, effective and convenient regimen for first line treatment in advanced NSCLC. Alopecia is preventable in pts who accept scalp cooling.

P2-290 **NSCLC: Cytotoxic Chemotherapy Posters, Tue, Sept 4**

Phase II study of S-1 in non-small cell lung cancer (NSCLC) patients previously treated with a platinum-based regimen

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Background: S-1, an oral fluoropyrimidine derivative, has been shown to exhibit antitumor activity against chemotherapy-naïve NSCLC. It has been reported that S-1 has anti-angiogenic effect. The aim of this study was to evaluate the efficacy and safety of S-1 for previously treated NSCLC and to assess the relation between the efficacy of S-1 and number of circulating endothelial cell (CEC).

Methods: Patients with histologically or cytologically confirmed NSCLC, 20 to 80 years old, performance status (PS) 0-2, who underwent platinum-based chemotherapy, were eligible. S-1 (80mg/m^2/day) was administered twice a day on days 1-28 every 6 weeks for two to four courses. The primary endpoint was the response rate (RR). Assuming that a RR of 20 % in eligible patients would indicate a potential usefulness of the regimen while a rate of 5 % would be the lower limit of interest and that alpha = 0.05 and beta = 0.20, the estimated number of required patients was 27 (Simon's two-stage minimax design). Number of CEC was measured before treatment, on day 8, and 28. CEC was enumerated automatically as nucleated, CD146+, CD105+ and CD45- cells in 4 ml of peripheral blood.

Results: From June 2005 to May 2005, 27 patients (male/female: 21/6, median age: 62 years old, adeno/squamous/others: 17/7/3, PS 0/1/2: 13/13/1, prior chemotherapy regimens 1/2/3: 7/13/7) were enrolled. Five partial responses were observed, for the RR of 19% (95% confidence interval: 12-26 %). The median survival time was 10.2 months and the median progression free survival (PFS) was 3.4 months. Grade 3/4 leukopenia, neutropenia, and thrombocytopenia were observed in 4, 7, and 4%, respectively. Grade 3/4 non-hematological toxicities were fatigue (7%), infection (7%), appetite loss (4%), and diarrhea (4%). Although there was no relation between tumor response and CEC count, patients with < 50 CECs tended to have the longer PFS.

Conclusion: S-1 was active and tolerated for previously treated NSCLC and it was suggested that CEC count may correlate to the survival time.

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Results of a multicenter randomized phase II trial of two different combinations of docetaxel (D) and gemcitabine (G) and of cisplatin/gemcitabine (CG) followed by docetaxel as first line therapy for locally advanced or metastatic non small cell lung cancer (NSCLC)

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Background: Cisplatin is the cornerstone in advanced NSCLC, but the optimal sequencing of drugs and the role of non-cisplatin doublets remains to be defined. The aim of this phase II trial was to evaluate the response rate of two different schedules of D and G and of a third arm of GC followed by D.

Methods: Chemotherapy-naive stage IIIB (N3 or T4 pleural)/IV NSCLC patients (pts), ECOG performance 0-1, age 18-70 years received (Arm A) D (40mg/m^2 days 1-8) and G (1200mg/m^2 days 1-8) every 21 days, or (Arm B) D (50mg/m^2; days 1-15) and G (1500mg/m^2 days 1-15) every 28 days, both for a maximum of 6 cycles, or (Arm C) G (1200mg/m^2 days 1-8) and C (75 mg/m^2 day 2) for 3 cycles followed, in case of stable disease (SD), partial (PR) or complete response (CR) by D (75 mg/m^2 day 1) for 3 cycles, both every 21 days.

Results: From July 2002 to May 2004, 128 pts were enrolled (41 in Arm A; 46 in Arm B; 41 in Arm C). Pts characteristics: overall median age 61 years, PS 0 in 52%, stage IIIB in 19% of pts. A total of 704 cycles were given, 228 in arm A 208 in arm B and 268 in arm C respectively, Fifty percent and 68.5% of patients completed the treatment in arm A and C whereas only the 30.3 % in arm B. The major cause of treatment withdrawn was progressive disease (20.3%; 30.3%, 16.7% in arm A, B, and C respectively). Treatment withdrawn for adverse events occurred in 7.4% 10.7% and 3.7% in arm A, B, and C, respectively. Toxicity (by cycles) according to WHO criteria was mainly hematological, consisting of grade 3-4 neutropenia in 86 (17%) cycles (16/25/45) with less than 1% of febrile neutropenia and grade 3 thrombocytopenia in 19 (4%) cycles (6/2/11). Anemia g3-4 was present only in arm C in 5 cycles (1%). Non-hematologic toxicity was generally mild across

