were accrued at 32 sites between April 2004 and January 2006. Treatment consisted of VRL 25 mg/m^2 IV or 60−80 mg/m^2 oral plus GEM 1200 mg/m^2, days 1, 8 every 21 days. Activities of daily living (ADL), instrumental activities of daily living (IADL) and comorbidities were evaluated. DNA samples were collected from primary tumors for the assessment of microtubule associated protein 4 (MAP4) and from serum for checkpoint with forkhead-associated and ring finger (CHFR) methylation.
Results: Data on 130 p is available for toxicity and 95 for response. Median age 76 years (69−83); males: 86.8%; smokers: 70.5%; PS 0−1: 83.9%; adenocarcinoma: 34.4% / squamous: 48%; stage IIIB: 22.7%, IV: 77.3%. Self-sufficiency in ADL and IADL was 77.4% and 45.2% of the p analyzed. 68% of the p had comorbidities. Median cycles: 3 (1−8). 461 cycles (cy) were performed, 16.3% were delayed and 2.1% had dose reduction. Hematological toxicities: neutropenia grade 3−4, 12.5% p (4.1% cy); thrombocytopenia grade 3−4, 3.1% p (1.3% cy); grade 3 anemia, 3.1% p (0.9% cy). Efficacy in evaluable population: PR, 23.2% (95% CI, 15.1% to 32.9%); SD, 41.1%. 24 p died during the treatment period (non toxicity related) and 21 p were not evaluable. With a median follow-up of 5.8 months, median survival for the whole population was 4.97 months (mo), progression free survival 4.53 mo, event free survival 3.43 mo, 1-year survival 26.6%. Statistically significant differences in median survival were observed among subgroups: PS 0−1/2, 6.5 m vs. 2.3 mo ($p < 0.001$); gender male/female, 4.5 vs. 9.7 mo (p 0.027); ADL <6/=6, 3.4 vs. 7.1 mo (p 0.023).
Conclusions: The combination of VRL and GEM is effective, presenting a favourable response/toxicity ratio in elderly p with advanced NSCLC. A genomic analysis is ongoing.

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Level of circulating endothelial progenitor cells is a potential surrogate marker in human non-small cell lung cancer

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Vascularization is a key mechanism in non-small cell lung cancer (NSCLC) progression, and is frequently used as a prognostic factor. Until recently, it was generally accepted that the vascularization of tumors arise exclusively from the sprouting of preexisting capillaries. However, recent evidence suggests that tumor vasculature can also arise through vasculogenesis, a process by which bone marrow-derived endothelial precursor cells (EPCs) are recruited and differentiate in situ into mature endothelial cells to form new blood vessels. We assessed the quantity of circulating EPCs in the peripheral blood of 53 NSCLC patients by flow cytometry, and studied the incidence and contribution of EPCs to the vasculature of tumors. Precursor cells were detected by EPC-specific markers: CD34, vascular endothelial growth factor receptor 2 (VEGFR2, KDR), and CD133. Before therapy, no significant associations between EPC levels and standard prognostic parameters, as tumor stage, smoking history, histologic type, were detected. In NSCLC patients before anticancer treatment, the number of CD34+/VEGFR2+ EPCs in peripheral blood was significantly higher than in healthy controls (1162.4$\pm$242.4 vs. 345$\pm$54.8/mL). In the subgroup of responders to treatment (patients who achieved a tumor-free status with surgery and those with complete or partial response to chemo- or chemoradiotherapy), the mean number of EPCs/mL of blood (776.1$\pm$265) was significantly lower than in non-responders (patients with local recurrence or stable/progressive disease, 4687.9$\pm$1178.6). Our cases were also classified into two groups; EPC high or low, with a cutoff of 1000 EPCs/mL. Patients with low levels of circulating EPCs had significantly longer survival than those with high levels of EPCs (median survival: 55.5 weeks vs. 26 weeks, respectively). According to multivariate analysis, circulating EPC numbers predicted outcome independent of other variables. Our study indicated that EPCs are involved in the angiogenesis/vasculogenesis of NSCLC. However, it still remains to be determined whether EPC level can be used as a surrogate marker to monitor the efficacy of standard or antiangiogenic therapies in NSCLC.
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Influence of baseline inflammatory markers on the response to first-line chemotherapy in advanced NSCLC

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Background: Recent studies have shown that the presence and a magnitude of inflammatory response, as evidenced by concentration of circulating C-reactive protein (CRP) is a prognostic factor independent of age, stage, PS, weight loss and hypoalbuminemia in patients with NSCLC. Our retrospective analysis demonstrated that high baseline CRP and white blood cell count (WBC) correlate with a poor prognosis in NSCLC patients (ASCO, 2006).
Materials and Methods: We conducted a prospective validation study to confirm previous findings and to explore the relationship between baseline CRP and WBC with response to 1st line chemotherapy (CTX) in pts with newly diagnosed NSCLC with stages 3B, 3B pleural effusion and 4. 69 patients with non small lung cancer had CRP and WBC measured prior to their 1st treatment. Pts were enrolled between February 2005 and October 2006 and were assigned a prognostic index (PI) score of 0 if CRP $\leqslant$ 10 mg/L and WBC $\leqslant 11\times10^9$/L, 1 if one of the markers was elevated, or 2 if both were elevated. Response was measured by chest CT following two cycles of CTX.
Results: 24 (35%) pts had PI of 0; 31 (45%) patients had PI of 1, and 14 (20%) patients had PI of 2. Survival analysis demonstrated that patients with PI of 0 had a median survival of 19.9 mo (CI: 10.5−29.3); patients with PI of 1 had 10 mo (CI: 6.4−13.8) survival, while patients with PI of 2 had 3 mo (CI: 2.5−3.3) survival ($p < 0.001$). 12/32/25 pts had a PR/SD/PD after 1 (7pts) or 2 (62 pts) cycles of chemotherapy. There was a significant but fairly weak correlation between PI and disease progression. Baseline CRP level was 2 fold higher in pts who progressed compared to those who did not progress (56 mg/L vs 23 mg/L). 9/14(64%) with PI of 2 developed progressive disease, compared to 7/24(29%) with PI of 0 and 9/31 (29%) with PI of 1 ($P < 0.05$, $r = 1.3$). In the analysis of prognostic factors for survival using COX regression model the age, sex, stage, ECOG PS and PI were included. The PI had an excellent predictive power in estimating survival. The hazard for death increased 3.3 fold for each unit increase in PI value ($p < 0.001$).
Conclusion: We conclude that patients with an aberrant inflammatory response as reflected by a combination of high CRP and WBC had significantly shorter survival. Correlation with response to treatment requires further investigation.
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Analysis of the progostic value of the quantification of plasmatic epidermal growth factor receptor (EGFR) in advanced non-small cell lung cancer (NSCLC) patients

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Background: EGFR has an extracellular ligand-binding domain that can be proteolitically cleaved from the cell surface and can be accurately quantified in blood by ELISA. We have investigated the usefulness of plasma EGFR measurements as prognostic marker in advanced NSCLC.
Materials and Methods: The cohort consisted in 329 patients (p) with advanced NSCLC that received first-line therapy with cisplatin and docetaxel. The concentration levels of the EGFR extracellular binding domain were determined by a sandwich quantitative ELISA in the baseline, before therapy.
Results: Median age was 61, range [39−80], 84% males, 100% caucasian, 68% stage IIIB and 32% IV and 99% PS 0−1. The histological subtypes were: 31% squamous cell carcinoma, 49% adenocarcinoma, 15% large cell, and 5% undifferentiated. 181 p achieved complete response (CR), partial response (PR) or stable disease (SD) and 109 p progressive