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Disease stabilization (SD) as a surrogate end-point in advanced non-small-cell lung cancer (NSCLC) patients treated with erlotinib (E) or gefitinib (G)

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Background: One retrospective study (Hotta K, Ann Oncol 2005), investigating the prognosis of patients (pts) obtaining SD as best response with G treatment, has demonstrated that both progression-free survival (PFS) and survival (S) were significantly longer than those in pts with progressive disease (PD). The aim of this retrospective study was to compare the PFS and S outcome in pts with advanced NSCLC who achieved SD or partial response (PR) after treatment with E or G.
Materials: Pooled data from 62 pts, entered into an expanded access program of E (n = 31) and a compassionate-use program of G (n = 31), were retrospectively analyzed. E and G were given orally at 150 and 250 mg per day respectively and were continued until disease progression, development of unacceptable toxicity or patient's refusal.
Results: Pts characteristics: median age 69 years (42−85); females = 21 pts (34%); never/former smokers = 16/38 pts (26/61%); adenocarcinoma/BAC = 35/10 pts (56/16%); PS 0/1 = 18/38 pts (29/61%). In 16 pts (26%) E or G were given as first-line therapy; 21 pts (34%) had received $\geqslant$2 prior lines of chemotherapy. Six pts (10%) achieved a PR and 18 pts (29%) obtained SD. TTP and OS in pts obtaining PR and SD were comparable: 7 vs 5.5 and 9.7 vs 9.1 months respectively. In progressing pts median TTP and OS were 1.7 and 3.7 months. No difference in response, TTP and S between E and G were demonstrated.
Conclusions: Our findings indicate the importance of achieving disease control with both E and G treatment. Pts obtaining SD with E or G had a similar PFS and S compared with those having PR.
An analysis of the role of mutational status and other biomarkers in predicting clinical outcome is currently underway.

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Prognostic factors for radical treatment of stage III NSCLC

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Purpose: To analyze potential factors predicting for improved outcome after radical treatment for Stage III NSCLC.
Methods: Retrospective review of stage III NSCLC patients treated with concurrent chemoradiation with or without resection at DFCI/BWH with curative intent was done with IRB approval. Patients undergoing induction chemotherapy (2 cycles or greater) were excluded. Patients were followed for any local or distant failure and overall survival. Univariate analysis was done with Fisher's exact test and multivariate Cox logistic regression analysis was done to determine factors predictive of treatment outcome.
Results: Between 8/00 and 11/06, 88 patients were identified who received concurrent chemoradiation (CRT) for stage III NSCLC. 52/88 pts were male (59%). Median age was 61 (range 33−81). 35 (40%) were stage IIIA and 53 (60%) stage IIIB. Chemotherapy given concurrently with radiation was weekly carboplatin/paclitaxel (TC) in 51 pts (58%) and every three week EP in 37 pts (42%). 60 (68%) patients were treated with CRT alone and 28 (32%) patients were treated with neoadjuvant CRT followed by resection. Among the resected patients 18/28 were stage IIIA, 10/28 were stage IIIB. Median follow-up for all pts was 12.5 mos (range, 3−64 mos.) Median follow-up for patients undergoing resection was 18.5 mos vs. 10.5 mos for those who did not undergo resection. Median overall survival is 18 mos. Median time to local and distant failure was 23 and 12 months respectively. Actuarial 1 and 2-yr overall survival was 65% and 44%. On univariate analysis: stage and performance status, use of surgery and TC chemotherapy were all predictive of improved survival. On multivariate analysis: only performance status (0&1 vs. 2+) (HR 0.32; p = 0.02) use of TC chemotherapy (HR 0.39; p = 0.003) and most significantly surgical resection (HR 0.085; p < 0.0001) were predictors of improved survival. There were no post-operative deaths in any of the resected patients. 1 and 2-yr local and distant control rates were 68% and 48%; 48% and 38% respectively. Stage and use of surgery were both significant predictors of local and distant control on multivariate analysis.
Conclusions: Stage III NSCLC is a heterogeneous group of patients and it is difficult to draw firm conclusions from a retrospective analysis. However, in this series, those patients who could underwent resection, had improved outcome after induction CRT.

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Hypofractionated/ accelerated radiotherapy with cytoprotection (HypoARC) combined with vinorelbine and liposomal doxorubicin for locally advanced non-small cell lung cancer (NSCLC)

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Introduction: Combined radio-chemotherapy is the standard therapeutic approach for patients with locally advanced non-small cell lung cancer (LA-NSCLC). In the present study we examined the feasibility of HypoARC combination with vinorelbin and liposomal doxorubicin.
Patients and Methods: Fourteen patients (pts) with LA-NSCLC (PS 0−2) were recruited in a dose escalation protocol of oral vinorelbine during radiotherapy. Patients received 15 fractions for 3.5 Gy within four consecutive weeks (1 week split after the 10th fraction), supported with subcutaneously administered amifostine (500–1000 mg/day). Liposomal doxorubicin was administered at a standard dose of 20 mg/m^2 every two weeks, for 3 consecutive cycles. Vinorelbine was escalated at 3 dose levels: a. 20 mg/m^2 every week (5 pts), b. 25 mg/m^2 thrice every two weeks (5 pts) and c. 30 mg/m^2 thrice every two weeks (4 pts).
Results: Grade 3 neutropenia enforcing chemotherapy delays was noted in 2/5 and 2/4 patients in the groups 'b' and 'c' respectively. Fatigue was a common, but not a dose defining feature. Radiation grade 2 esophagitis was noted in 6/14 patients. No case of severe radiation pneumonitis was noted. Partial response was documented in 13/20 (65%) patients, minimal response in 3/20 (15%) and stable or progressive disease in 4/20 (20%). The median local progression-free survival was 12 months and the median overall survival 8 months.
Conclusion: It is concluded that the administration of 25 mg/m^2 of vinorelbine thrice a week together with liposomal doxorubicin and thoracic radiotherapy is feasible for patients with LA-NSCLC. Further studies are demanded to better assess benefits in terms of local and distant control of the disease.

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Biweekly paclitaxel as second-line treatment in advanced non-small-cell-lung-cancer (NSCLC). A phase II study of the Galician Lung Cancer Group

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Background: Paclitaxel is an active drug for NSCLC. Our purpose was to evaluate the efficacy and toxicity of biweekly administration of this drug in previously treated patients with advanced NSCLC.
Materials and Methods: Patients with stage IIIB and IV NSCLC, which progressed after or during first-line chemotherapy, measurable disease, ECOG PS=0−1 and adequate organ function were included. Paclitaxel was administered at 150 mg/m^2 iv, days 1 and 14, every 28 days, for a maximum of six cycles. Both, toxicity and efficacy analyses, were performed on the intent-to-treat (ITT) population.
Results: Between September 2004 and November 2006, 45 patients (M/F, 42/3) were included, with median age 62 years (39−79). Tumor histology mainly included epidermoid (42.2%) and adenocarcinoma (35.6%). Tumor stage was IIIB (24.4%) and IV (75.6%). Median number of metastatic lesions was 1 (57.8%), located mainly in lymph nodes (44.4%), lung (33.3%), adrenal glands (20%) and bone (13.3%). Previous chemotherapy included platinum (80%), docetaxel (64.4%) and gemcitabine (57.8%). A total of 251 cycles (median 5, range 1−6) were administered. Median relative dose intensity was 96.2%. Toxicity: Grade III/IV hematologic toxicities per patient were neutropenia (2.3%) and anemia (2.3%). Grade III/IV non-hematologic toxicities were asthenia (2.3%), arthralgias/myalgias (2.3%) and peripheral neuropathy (2.3%). Efficacy: Of 45 ITT patients, 9 achieved PR, 11 SD and 17 progressed, resulting in an ORR of 20% (95% CI: 8.3−31.7%). 7 patients could not be evaluated due to early withdrawal (4 tumor-related exitus, 1 PS deterioration, 1 hypersensibility reaction and 1 loss of follow-up). With an average follow-up time of 286 days, median TTP and OS were 174 days (95% CI: 137.6–210.4) and 289 days (95% CI: 140.5–437.4), respectively.
Conclusions: Biweekly paclitaxel is an active and very well tolerated regimen in previously treated patients with advanced NSCLC.