Characteristics of patients: There were 65 men (58.6%) and 46 women (41.4%). Mean age was 61.0 years (27.0−86.0). Twenty three patiens (20.7%) were neversmokers, 64 (57.7%) former smokers and 22 (19.8%) smokers. Adenocarcinoma was diagnosed in 48 patiens (43.2%), bronchoalveolar carcinoma (BAC) in 10 (9.0%), squamous cell carcinoma in 37 (33.3%), NSCLC without further details in 13 (11.7%) and large cell carcinoma in 3 (2.7%). Performance status (PS) at the start of treatment was 0 in 12 patient (10.8%), 1 in 79 (71.1%) and 2 in 20 patients (18%). Erlotinib treatment was started after failure of preceding chemotherapy in almost all patients (93.5%).
Results: Only 36 from 111 patients (32.4%) have active therapy of erlotinib and they have therapeutical response. The treatment was stopped in 75 patients (67.6%) for progression of disease in 52 patients (68%), in 9 patients (12%) stopped for adverse events, eight patients (10.6%) died during follow up. In 50 patients (45.0%) was started therapy with erlotinib in second line therapy, in 54 patients (48.6%) in third line therapy, in 6 patients (5.4%) in first line therapy. Best objective response was PR in 13 patiens (11.7%) and SD in 45 (40.5%). Progression of the disease was found in 52 patients (46.8%). It was interesting that improvement in at least one of symptoms was noticed sooner than objective response. Median survival time was 5, 7 months from the beginning of erlotinib treatment for part of died patiens, while one-year live 33% patients and six month live 47.9% patients.
Conclusions: Our results are in comparison with published data. Several phase II and III clinical trials with 150 mg erlotinib testing its efficacy in advanced NSCLC patients have been performed. In 57 previously treated patients with EGFR-expressing NSCLC, the response rate (RR) to erlotinib was 12.3%. Responses were seen regardless of the number of prior chemotherapy regimens. The median survival was 8.4 months, and the 1-year survival was 40%. Till the present time there have been no method to determine the group of patient with NSCLC, that has clear benefit from erlotinib treatment.

9134 POSTER

Phase II study of topotecan and bevacizumab in patients with metastatic non-small cell lung cancer who have failed prior systemic chemotherapy – interim analysis

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Background: Previous studies have suggested improved outcomes for chemotherapy naïve advanced non-small cell lung Cancer (NSCLC) treated with topoisomerase I inhibitor. Bevacizumab in combination with carboplatin and paclitaxel is approved for NSCLC in first line therapy. There is no clinical data describing safety and efficacy of topotecan and bevacizumab combination. The objective of this study was to evaluate the response rate and toxicities of the combination of IV topotecan and bevacizumab in patients with stage IIIB/IV NSCLC who have failed prior systemic chemotherapy.
Materials and Methods: Twenty-six patients were enrolled between 10/2006−1/2009 in this Phase II trial. All patients received topotecan 4.0 mg/m^2 IV per day on days 1, day 8 and day 15 and bevacizumab 10 mg/kg IV was given day 1 and 15. Treatment was repeated every 28 days Treatment was repeated every 28 days in the absence of disease progression or unacceptable toxicity. Response assessment (using RECIST) was performed every two cycles.

Table 1

Characteristics	No.	%
Male/female	12/14	46/54%
Age (yrs), median (range)	66 (38−81)	
Race		
White	24	92
Asian	2	8
Histology		
Adenocarcinoma	26	100
Stage IV	26	100
Smoking (smoker = 20 PY)		
Current smoking	1	4
Quit >20 yrs	2	8
Quit <20 yrs	12	46
Non smoker	11	42
Previous lines of chemotherapy (range)	2.5 (1−5)	
Treated Brain Mets	6	23
# months elapsed since brain Tx (range)	10.5 (2−31)	
Total	26	

Results: Patients' characteristics were shown in table 1. There were 6/26 (23%) partial responses and 15/26 (58%) stable diseases with an overall response rate of 81%. Median progression free survival in responder was 8.9 months and 4.4 months in patients with stable disease. Median overall survival of 12.5 months (95% CI, 9.4−15). The most common nonhematologic toxicities were fatigue, headache, nausea and hypertension and most of <3 grade (G). One patient had G 3 fatigue; one had G 4 hyperuricemia and one patient with Gaucher's disease and thrombocytopenia had G V hemoptysis. Hematological toxicities were manageable with G 3 neutropenia in 5 (19%), G 3 thrombocytopenia in 4 (16%), and G3 anemia in 1 (4%). The treatment combination was tolerable even in patients with history of brain metastatic disease (23%) and patients 70 yrs or older (39%).
Conclusions: The combination of topotecan and bevacizumab appears to be effective and safe for patients with metastatic non-squamous non small cell lung carcinoma. Further accrual to this study is warranted.

9135 POSTER

Erlotinib as maintenance therapy after platinun-based chemotherapy in advanced non-small-cell lung cancer (NSCLC): a phase II trial

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Background: We conducted this prospective phase II trial to evaluate the efficacy and toxicity of the sequential therapy of erlotinib in advanced NSCLC patients (pts) without progression after platinum-based chemotherapy (CT).
Material and Methods: Eligibility criteria: advanced NSCLC, Performance status (PS) 0 or 1, adequate renal, hepatic and bone marrow function, no progressive disease after ending chemotherapy. Treatment consisted on: erlotinib 150 mg/day starting 3−4 weeks after last day of CT until progression or unacceptable toxicity. Safety and Response was evaluated monthly.
Results: 47 pts were enrolled, 42 (89%) stage IV and 5 (11%) wet stage IIIB, all valid for response and toxicity. The median age was 62 years (range: 39–77) with 39 (83%) males and 8 (17%) females. Histology subtypes: adenocarcinoma 28 pts (61.7%), bronquioloalveolar 3 pts (6.4%), large cell 3 pts (6.4%) and squamous cell 12 pts (25.5%). PS 0 was found in 23 pts (49%) and PS 1 in 24 pts (51%). 38 pts (81.9%) completed at least six cycles of chemotherapy. The response to CT was: CR: 1 pt (2.1%), PR: 24 pts (51.1%), ED: 22 pts (46%). Sequential erlotinib improved response in 6 pts (12.8%), in 23 pts (48.9) prolonged stabilization, and 18 pts (38.3%) had progression. The median time to progression (TTP) and survival (OS) were 9.4 months (m) (95% CI, 4.96−13−84), and 19.23 m (95% CI, 8.82−29.64) respectively. No significant differences in TTP were found according to age, sex, PS, histology or previous response to chemotherapy, but yes depending on response to erlotinib: PR: 31.5 m (95% CI 15.37−47.63), EE: 12.8 m (95% CI, 10.58−15.03), Progression: 6.3 m (95% CI, 5.36−7.3), $p < 0.001$; and moreover depending on smoking status: Never: 21.67 m(95% CI, 5.39−37.94), previous smoker > 5 years: 14.03 m(95% CI, 10.77−17.30), previous smoker 1 year: 7.77 m(95% CI, 7.62−7.91), current smoker: 5.9 m(95% CI, 5.12−6.34), $p < 0.001$. In Cox-regression model, again smoking status ($p < 0.001$), and response to erlotinib ($p = 0.002$) were associated with a significant difference in TTP. Very similar results respect OS, although in Cox-regression model only never smoker or more than 5 years previous smoker patients had a significant better survival. Toxicity: The most frequent side effect was skin rash, grade (g) 1 in 11 pts (23.4%), g 2 in 16 pts (34%) and g 3 in 3 pts (6.4%). Only 1 pt had diarrea g 3, and no other significant side effects were observed. We found a significant benefit in pts with g 2−3 skin toxicity respect those with g 0−1, in both TTP($p = 0.0003$) and OS ($p = 0.0014$).
Conclusion: Erlotinib administered as maintenance therapy after platinum-based CT had promising results. Pts with the best benefit were those with response to erlotinib, in never or past (more than 5 years) smokers and with g 2−3 skin toxicity