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Health-related quality of life (HRQOL) with sunitinib (SU) as maintenance therapy following carboplatin (C) and paclitaxel (P) treatment for locally advanced or metastatic non-small cell lung cancer (NSCLC)

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Background: SU is an oral, multitargeted tyrosine kinase inhibitor of VEGFRs, PDGFRs, KIT, FLT3, CSF-1R, and RET. An open-label, multicenter, phase II trial was conducted to study SU as maintenance therapy following first-line treatment with C/P in patients (pts) with stage IIIB/IV NSCLC. We report HRQOL data during C/P treatment and the SU maintenance period from this trial [NCT00113516: Pfizer].
Materials and Methods: Pts received P (175−225 mg/m^2) plus C (AUC = 6 mg·min/mL) for 4 cycles followed by SU maintenance monotherapy (50 mg/d in 6-wk cycles: 4 wks on treatment, 2 wks off). HRQOL was assessed using EORTC QLQ-C30 and QLQ-LC13. Questionnaires were completed on day 1 of each C/P treatment cycle and days 1 and 28 of each 6-wk SU cycle. The long-term effect of C/P and SU on global quality of life (GQL), functioning, and symptom scales were examined with longitudinal models to compare difference in mean changes from baseline between C/P and SU treatment during corresponding cycles. The short-term effect of SU was examined with paired t-tests to compare mean change on-treatment versus off-treatment periods at cycle 1.
Results: A total of 84 pts received C/P, and 66 pts received SU maintenance therapy. Long- and short-term data were available for 36 and 29 pts, respectively. Relative to C/P, SU following C/P was suggestive of long-term improvements in emotional functioning (cycle 4, +14.2 points, $p = 0.08$), social functioning (cycle 4, +20.3 points, $p = 0.07$), fatigue (cycle 3, −13.9 points, $p = 0.06$; cycle 4, −21.3 points, $p = 0.04$), dyspnea item in C30 (cycle 4, −15.1 points, $p = 0.09$) and dyspnea scale in LC13 (cycle 4, −20.6 points, $p = 0.03$). Long-term worsening symptoms included diarrhea (cycle 1, +7.8 points, $p = 0.06$; cycle 2, +24.5 points, $p < 0.01$) and sore mouth (cycle 1, +10 points, $p = 0.04$). Statistically significant improvements ($p < 0.04$) were observed for peripheral neuropathy and alopecia due to cessation of C/P in nearly all visits. Short-term worsening in HRQOL at cycle 1 of SU treatment included fatigue (+7.4 points) and sore mouth (+13.3 points) while improvements included cognitive functioning (+6.1 points) and arm and shoulder pain (−8.0 points); all $p < 0.05$.
Conclusions: While there were increases in some treatment-related symptoms, this study found that SU maintenance treatment after C/P may also lead to some long-term improvements in HRQOL and functioning. SU maintenance therapy may be a feasible treatment option for pts with advanced NSCLC.

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Cetuximab in combination with gemcitabine/docetaxel or carboplatin/gemcitabine in chemonaïve patients with advanced non-small cell lung cancer: toxicity data from an ongoing Phase II/III trial (GemTax IV)

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Background: The EGFR-targeting antibody cetuximab has been shown to be effective in lung cancer. Our randomized trial assesses the safety profile of cetuximab in combination with two different chemotherapy regimens.
Methods: Patients with histologically confirmed stage IIIB or IV NSCLC, WHO PS 0−2, and no prior chemotherapy received cetuximab with 400 mg/m^2 as starting dose followed by 250 mg/m^2 weekly either combined with gemcitabine 1000 mg/m^2 at days 1 and 8 for 2 cycles (3qw) followed by docetaxel 75 mg/m^2 at day 1 for 2 cycles (q3w) (arm A) or carboplatin AUC5 at day 1 combined with gemcitabine 1200 mg/m^2 at days 1+8 for 4 cycles (q3w) (arm B). Maintenance cetuximab therapy was administered weekly until disease progression or unacceptable toxicity.
Results: 273 evaluable patients received 2255 cetuximab infusions combined with chemotherapy and 1591 infusions of maintenance cetuximab. Patient characteristics were balanced between treatment arms with 73% male patients of median age 64 years (range 36−80), 37% of WHO PS 0 and 56% of PS 1, and 84% had tumor stage IV. 49 patients in arm A received 1−26 cycles of maintenance cetuximab (8 patients >10 cycles); 61 patients in arm B received 1−23 cycles (7 patients >10 cycles). Grade 1 or 2 skin 0reactions related to study medication occurred in 83% of patients in arm A and 77% in arm B. In general, hematological toxicity was more common in patients receiving carboplatin; leukopenia and neutropenia occurred in more than 30% of patients, pneumonia and fever occurred in ~10% of patients; thrombopenia without intervention in 40% of patients, and allergic reactions in 5% of patients. Toxicities requiring clinical intervention are shown below.

	Arm A		Arm B	Maintenance
	Cetuximab plus gemcitabine (n = 136)	Cetuximab plus docetaxel (2nd part of the sequence) (n = 82)	Cetuximab plus gemcitabine/ carboplatin (n = 137)	Cetuximab maintenance (n = 110)
Total number of cycles	241	141	428	565
Median number of cycles	2	2	4	3
Grade 3/4 anemia + ⩾ 1 blood transfusion during treatment cycle (%)	<1	1	2	
Grade 3/4 thrombocytopenia + ⩾ 1 platelet transfusion during treatment cycle (%)	<1		6	
Grade 3/4 febrile neutropenia + IV antibiotics during treatment cycle (%)	<1	4	1	
Skin rash any (severe) (%)	56 (5)	21 (5)	38 (5)	8 (<1)

Conclusions: Cetuximab does not increase chemotherapy toxicity in the induction phase, and is well tolerated in the maintenance phase. Skin rash developed in about 80% of patients, and occurred early during treatment in most cases.

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Bevacizumab (B), cisplatin and vinorelbine in chemo-naïve patients (P) with non squamous non small cell lung cancer (NSCLC): a galician lung cancer group phase II study

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Background: Bevacizumab, an anti-VEGF monoclonal antibody, improves response rates and prolongs survival in p with non squamous NSCLC when combined with carboplatin-paclitaxel or cisplatin-gemcitabine. This single-arm, open-labeled phase II trial aims to evaluate the efficacy and safety profile of B in combination with another widely used chemotherapy doublet for NSCLC: cisplatin and vinorelbine.
Methods: Chemotherapy-naïve p diagnosed with stage IIIB or IV non squamous NSCLC received cisplatin (80 mg/m^2), vinorelbine (25 mg/m^2 IV days 1 and 8) and B (15 mg/kg IV) on day 1 every 3 weeks for up to 6 cycles followed by B 15 mg/kg alone every 3 weeks until disease progression. Main eligibility criteria were: PS 0−1, no brain metastases, no history of hemoptysis, stable cardiac condition and no full dose anticoagulation Primary endpoint was progression-free survival and secondary endpoints were RR, duration of response, OS, 1-year survival and safety profile of the combination.
Results: 49 p have been enrolled in the study and data of 27 p have been included in this analysis. P characteristics were: male 66.7%; median age 57 years (range 41−74); ECOG PS 0/1 (%) 33.3/66.7; adenocarcinoma/other (%) 74.1/25.9; stage IIIB/IV (%) 25.9/74.1. Median number of cycles for B/cisplatin/vinorelbine was 4.0 (range 1−6) and median number of cycles for B maintenance was 2 (range 1−4). 17 p were