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An Interim Analysis of Health-Related Quality of Life (HRQoL) in Patients With Non-Squamous Non-Small-Cell Lung Cancer (nsNSCLC) Receiving Bevacizumab Vs Bevacizumab + Pemetrexed for Maintenance Therapy in AVAPERL 1

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Background: Bevacizumab (bev) + pemetrexed (pem) in maintenance (mtc) therapy may improve tumour control and progression-free survival in patients with nsNSCLC. The objective of this analysis was to detect and compare changes in HRQoL during the Roche sponsored AVAPERL 1 study (MO22089) and was based on preliminary data (cut-off 11 February 2011).
Material and Methods: Patients (n = 373) with IIIB or IV nsNSCLC received first-line induction therapy bev–pem–cisplatin every 3 weeks for 4 cycles. Patients with at least stable disease were randomised to receive bev (n = 128) or bev+pem (n = 129) until disease progression or unacceptable toxicity. European Organisation for Research and Treatment of Cancer (EORTC) QLQ-C30 and QLQ-LC13 questionnaires were used to assess HRQoL. A difference $\geqslant$10 points was deemed a clinically relevant change. Results presented are calculated according to EORTC guidelines and standard HRQoL statistical methods.
Results: The analysis was performed on responses from the intent-to-treat population. At each cycle, $\geqslant$73% of patients (up to a maximum of 82%) returned completed questionnaires. Differences between treatment arms (bev+pem − bev) in mean change of HRQoL scores from pre-mtc baseline to respective cycle are summarised in Table 1 for all scales with $\geqslant$1 clinically relevant change from mtc baseline and 1 statistically significant difference between treatments.

Table 1: Differences between treatment arms (bev+pem − bev) in mean scores from pre-mtc baseline prior to specified mtc cycle

	mtc3	mtc5	mtc7	mtc9	mtc11	Favouring
QLQ-C30 Questionnaire						
Global health score/QoL scale	−6.7*	−5.7	−10.0*	−11.0*	−8.2	bev
Physical functioning	−3.1	−2.4	−8.9*	−12.8*	−3.4	bev
Role functioning	−5.0	−9.8	−22.3*	−20.6*	−18.6	bev
Nausea and vomiting symptoms	0.4	3.4	11.7*	21.1*	19.7	bev
Dyspnoea symptoms	2.6	7.5	10.6	17.1*	−9.8	bev
Appetite loss symptoms	4.1	10.2	22.6*	30.2*	31.0*	bev
Constipation symptoms	4.0	12.4*	8.2	14.1	21.0*	bev
QLQ-LC13 Questionnaire						
Peripheral neuropathy	4.2	6.3	9.3	22.4*	11.1	bev
Pain in arm or shoulder	−4.3	−8.9*	−7.2	−17.6*	−15.0	bev+pem

*95% CI indicates statistical significance

Conclusions: There might be a trend towards improved HRQoL with bev alone compared to bev+pem. Analyses on the mature dataset will be presented.

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Number of Treatment Lines Defines Prognosis in Advanced Non-Small Cell Lung Cancer (NSCLC) Patients − a Prospective Observational, Single Center Study

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Background: Despite recent achievements in advanced NSCLC treatment the current patients'(pts) prognosis remains poor. Decision making process in clinical practice is based only on a few prognostic/predictive factors. The study aimed to evaluate the disease-related and patient-related factors' impact and its magnitude on prognosis of pts with advanced NSCLC.
Material and Methods: Forty seven consecutive pts, man:woman (37/10), mean age 61.3 y (range 29−76) with stage IIIB/IV (10/37) NSCLC were admitted at the Department, for a period of two years. Twenty four patients- and disease-related parameters were estimated to be prognostic for progression-free (PFS) and overall survival (OS). Additionally, the neutrophil-lymphocyte ratio (NLR) and platelet-lymphocyte ratio (PLR) as markers of systemic inflammation response (SIR) were also measured. RESULTS: Mean OS of 12.04 mos (SD 10.76) and mean PFS of 6.45 (SD 5.4) mos were found. Six pts (14%) did not started chemotherapy because of rapid clinical deterioration. All the rest were symptomatic with ECOG PS 1. Half of the pts have undergone only one line of therapy, nearly one third (28%) − two lines, four pts (9%) have been treated with three or more therapeutic lines. Statistical significant difference in PFS ($p = 0.001$) and in OS ($p = 0.010$) was found between 17 progressed on first-line therapy (mPFS 4.06; mOS 8.65) pts and 21 non-progressed (m PFS 9.76; mOS 17.4). According to number of therapeutic lines pts differ strongly in their survival times (PFS, $p = 0.007$; OS, $p < 0.0001$) as follows: for untreated pts − mPFS 1.6$\pm$0.5 SD, mOS 2.2$\pm$0.9SD; for pts treated only with first line therapy − mPFS 5.4$\pm$5.0SD, mOS 9.3$\pm$5.4SD; for pts treated with two lines therapy − mPFS 9.6$\pm$5.6SD, mOS 14.0$\pm$7.1SD and for pts treated with three or more lines − mPFS 10.0$\pm$4.8SD, mOS 35.0$\pm$15.8SD. In univariate analysis in addition to number of therapeutic lines significant associations with prognosis for albumin, hemoglobin levels and response rates were detected. The median NLR and PLR were 3.95 and 225.7, respectively. Regarding SIR significant correlations with GGTP and ALP were found ($r = 0.78$, $p < 0.0001$ and $r = 0.74$, $p < 0.0001$,respectively).
Conclusions: Advanced, symptomatic NSCLC pts live longer when receive more than one lines of therapy. The lack of hypoalbuminemia, anemia and progressive disease also influence survival positively. Additional research is needed to specify the exact prognostic/predictive value of SIR.

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Anemia Due to Single Agent Pemetrexed, Requiring Transfusions, Despite Vitamin B12 and Folic Acid (FA) Supplementation

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Introduction: Pemetrexed is now increasingly being used for treating mesotheliomas and Non Small Cell Lung Cancer. Initially when reporting its use in patients with mesotheliomas, Vogelzang et al. (J Clin Oncology 2003;21:2636−44) described an incidence of 4.8% for anemia in combination with cisplatin. 86% of these patients received B12 and FA supplementation. It was not clear how many of the anemic patients were supplemented. Our study was undertaken to see if patients receiving pemetrexed and B12+FA supplementation develop anemia requiring transfusions.
Materials and Methods: All patients who received pemetrexed were identified from the Oncology Pharmacy database since year 2005. All these charts were retrospectively screened for use of pemetrexed, alone and in combination with platinum agents. Note was made of B12 and FA supplementation. Lab results were noted for hemoglobin (Hb) before starting and after receiving multiple doses of pemetrexed. Patients who received platinum agents and ones with incomplete data were excluded. Patients who had history of blood loss were also excluded.
Results: A total of 127 patients were identified who received pemetrexed alone or in combination with platinum agents (cisplatin or carboplatin). All patients received supplementation of vitamin B12 and FA during chemotherapy. 47 patients were excluded based on the above criteria. A total of 80 patients were included in the study, 76 received pemetrexed alone and 4 in combination with bevacizumab. 50% of patients were male (M) and 50% female (F). Average age of all patients was 57. A total of 56 (70%) patients developed anemia any grade. Grade 3 or 4 anemia was observed in 16 (20%) patients. This is much higher than previously described 4−5%. 18 patients (22.5%) received blood transfusion with a M:F ratio of 1:1 and average age 59.9. The average MCV of these patients was 89.6. More patients received transfusions than described under grade 3 or 4 anemia due to symptoms. Average number of cycles in patients needing transfusion was 4.8.
Conclusions: We observed that single agent pemetrexed has a much higher incidence of anemia despite B12 and FA supplementation; especially grade 3 or 4 anemia requiring blood transfusions than previously described. This is an important observation to explain to the patient before starting therapy, as 1 in 4−5 patients may need transfusion, especially if combined with other agents with hematological toxicity. This finding also needs to be studied more closely in prospective studies.