in patients with advanced non-small-cell lung cancer (NSCLC), and was assessed using the validated Lung Cancer Subscale (LCS). Protocol-specified symptom data analysis has previously been reported (Fukuoka M, et al. J Clin Oncol, In Press); however, further analysis was performed to assess the relationship between weekly LCS scores and radiographic response and survival.

Methods: In IDEAL 1, 210 patients were randomized to receive gefitinib 250mg/day or 500 mg/day. Of these, 140 patients (67 at 250 mg/day and 73 at 500 mg/day) were evaluable for SI, which was assessed weekly using LCS. Improvement was defined as an increase in LCS score of 2 or more points from baseline, for 4 or more weeks. Up to 4 LCS evaluations were performed prior to the first post-baseline radiological assessment.

Results: Overall compliance for the LCS was 74%. SI rates were similar for each dose group: 40.3% for 250 mg/day and 37.0% for 500 mg/day. SI significantly correlated with tumor response ($p<0.0001$). Overall, 78% of patients with complete response (CR) or partial response (PR), and 53% of those with stable disease (SD) reported SI. The median baseline LCS score was 18.0 (both doses). Improvement from baseline in mean LCS score was 3.0 (CI: 1.7-4.4), 1.3 (CI: 0.0-2.5), and 0.3 (CI: -0.7-1.3) for patients with PR, SD or progressive disease/unknown response, respectively.

Median overall survival for patients with and without SI was 9.9 and 4.8 months, respectively, and was 7.7 months for patients with SI without objective response.

Conclusions: This triadic analysis suggests that early symptom improvement and tumor response are related, and each contribute to predicting survival. Since the SI observed with gefitinib treatment predicts overall survival and tumor response, it is unlikely that SI was a result of a placebo effect. These results support those described for IDEAL 2 (Cella et al, ASCO 2003). Gefitinib demonstrates clinically meaningful SI that is complementary to a direct antitumor effect in patients with advanced NSCLC. 'Iressa' is a trademark of the AstraZeneca group of companies

920 POSTER

Protective activity of levo-thyroxine medication on iatrogenic hypothyroidism after radiotherapy for childhood cancer

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Objectives of the Study: RT is adopted in the treatment of the majority of pediatric cancers. Thyroid bed(TB) can be involved in the RT-fields while treating many tumors, i.e. CNS and cervico-splancnic primaries. The correlation between incidental/therapeutic exposition to RT and thyroid functional/parenchymal damages is well-known.

Methods Used: To limit the incidence of thyroid sequelae, we evaluated the protective effect of TSH suppression during RT.

Results: From January '98 to February 2001, 91 euthyroid pts potentially irradiated involving TB have been submitted to thyroid-sonography and evaluation of fT3,fT4,TSH and thyroglobulin at the beginning and at the end of RT; thereafter blood exam were done every six months and ultrasound after one year, then every other year. From day 7 before RT up to the end, pts were administered l-thyroxin at suppressive doses; every other day TSH suppression had to be checked as a value <0.3 μ M/ml. During subsequent f-up hypothyroidism was diagnosed as an elevation of TSH. Of the 91 pts, 61 were affected by CNS tumors (26 MBL,10 EPD,9 BST,6 glioma,4 others), 13 by HD, 8 by RMS and 8 by others. At last f-up, 63 are alive, 46/63 have been really irradiated on TB and, while 20 have been correctly TSH-suppressed during RT, 26 have not. Twenty-one/46 suffer iatrogenic hypothyroidism after a median of 14 mos from RT. Hypothyroidism-free survival is at 1 and 2 year after RT of 95%/95% for the suppressed-group and 85%/68% for the non-suppressed-group, respectively (p 0.12).

Conclusions: Hypothyroidism after RT on TB remains common also after TSH-suppression, however a trend toward a positive protective effect of this prophylactic attempt has been shown. Considering the feasibility, low costs and absence of side-effects, this trial needs to be verified on a wider number of patients through a randomized study.

921 POSTER

Is there an optimal target hemoglobin level for improved quality of life in cancer-related anemia?

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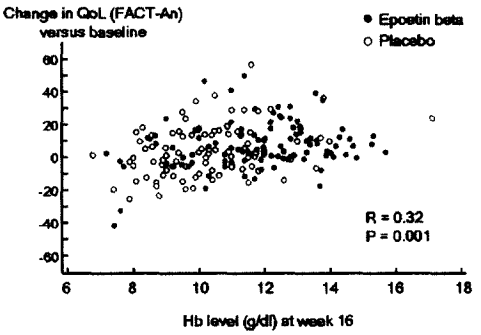
Background: Anaemia is common complaint in cancer patients, and adversely affects their quality of life (QoL). However, to what threshold the Hb must be raised to obtain a maximum QoL benefit remains unclear. Crawford et al (Cancer, 2002) demonstrated a direct relationship between haemoglobin (Hb) increase and improved QoL, and concluded that a Hb >12 g/dl should provide the best QoL improvement. We conducted a randomised placebo-controlled study to assess the effect of epoetin beta on anaemia and QoL in severely anaemic patients with haematological malignancies (Osterborg et al, JCO 2002). This study served as the basis for the current analysis of the relationship between changes in Hb level and QoL score at the individual level.

Materials and methods: In this randomised, double-blind, placebo-controlled study, patients with chronic B-cell malignancies (myeloma, low grade lymphoma and CLL), Hb levels of <10 g/dl and a repeated transfusion need, were enrolled. Epoetin beta (150 IU/kg) (n=170) or placebo (n=173) was administered subcutaneously three times weekly for 16 weeks. QoL was assessed at 4-week intervals using the Functional Assessment of Cancer Therapy Anaemia (FACT-An) questionnaire. The final Hb concentration and change in Hb, respectively, were plotted against the QOL change and final QOL score for each individual.

Results: At the study end, a greater improvement in FACT-An score was seen in the epoetin beta group versus placebo (change in mean score = 14.8 versus 8.7, $P<0.05$). Analysis of differences in FACT-An scores (see figure) between the responders to epoetin beta and non-responders revealed that the improved QoL was associated with a Hb increase of ≥2 g/dl from baseline (without transfusion). Although there was a statistically significant relationship ($P=0.001$, $r=0.32$) between the final Hb concentration and the change in FACT-An score, there was considerable inter-individual variability. In the individual patient, no optimal Hb level for QoL improvement could be identified.



Conclusions: Improved QoL in anaemic cancer patients was associated with an increased Hb of ≥2 g/dL (without transfusion). However, it remains open whether increased Hb concentration or fixed target Hb (i.e. 12 g/dL) should be recommended for optimisation of QoL with epoetin therapy.

922 POSTER

Lung changes following radiotherapy (RT) for breast cancer using high resolution computed tomography (HRCT) matched with 3D-treatment plan images, and functional tests.

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Background: Changes after postoperative RT for breast cancer were described but often without entering into details of subclinical damage and technical aspects of RT. This study aims to correlate changes at HRCT and functional tests with DVHs of 3D-treatment plan and find the possible prognostic factors. Method and materials: 45 patients (pts), aged 31-75 (median 55.8) after conservative surgery for breast cancer were entered. Exclusion criteria: respiratory disease, previous RT, age > 70, other cancers. Nine had smoke history. Pts received RT with 6 MV X-rays by tangential fields to total dose of 50 Gy, 2Gy/fx, and electron boost.