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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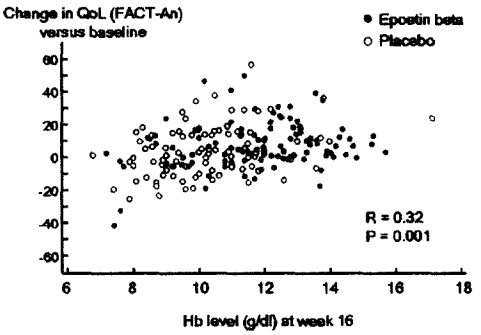
Background: Anaemia is common complaint in cancer patients, and adversely affects their quality of life (QoL). However, to what threshold the Hb must be raised to obtain a maximum QoL benefit remains unclear. Crawford et al (Cancer, 2002) demonstrated a direct relationship between haemoglobin (Hb) increase 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.

3D-treatment plan with DVHs for CTV and lung was obtained. Twenty-three pts had chemo and 14 hormone therapy. Pre-RT workup included HRCT and lung function tests. HRCT was performed by spiral CT with contiguous slices, 10 mm interval, 1 mm thickness from apex to diaphragm. Lung changes were scored 0-3. Lung function tests were: forced vital capacity (FVC), forced expiratory volume in 1 second (FEV-1), total lung capacity (TLC), forced expiratory flow at 25% of vital capacity (FEF-25) and diffusion capacity (DLCO). Plethysmography with constant volume was used. Tests were repeated 3 and 9 months after RT in 41/45 pts. HRCT slices were matched with RT-plan images.

Results: Pre-RT HRCT did not show any lung abnormality. Three months after RT, HRCT showed fibrosis in RT volume in 31/41 cases (76%): 44% grade I, 25% grade II, 7% grade III. At 9 months, fibrosis was seen in 32/41 pts (78%): 59% grade I, 19% grade II, 0% grade III. None developed clinical symptoms. Grade of fibrosis at 3 and 9 months correlated with RT volume (p=0.0096 and 0.0003 respectively). Changes at 3 and 9 months correlated to the dose of 25 Gy to volume >= 107 cm3 and 151 cm3 respectively. Pre-RT lung function tests were normal. All values decreased at 3 months: FVC and FEV-1 without and FEF-25 and DLCO with significance (p=0.029 and p=0.00006). At 9 months, FVC and FEV-1 showed recovery and FEF-25 and DLCO remained abnormal (p=0.026 and 0.0001 respectively).

Conclusion: This study confirms that RT does not induce clinically relevant lung injuries. HRCT and functional tests are able to detect subclinical changes: subpleuric fibrosis and reduction of functioning of bronchiole (FEF-25) and alveolar/capillary membrane (DLCO). Fibrosis correlates with volume receiving > 25 Gy. Age, smoke, chemotherapy, and hormone therapy were not prognostic factors.

923 POSTER

Clinical outcomes of palliative interventions for bowel obstructions in patients suffering from peritoneal carcinomatosis from non-gynecological cancer

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Background: The main aim of our study was to evaluate the clinicopathologic factors that predict outcomes after palliative operations for malignant bowel obstruction (MBO). This situation secondary to peritoneal carcinomatosis carries a poor prognosis.

Material and Methods: From four different surgical centers, data on patients undergoing laparatomy for palliation of gastrointestinal MBO, between 1998 and 2002 were retrospectively collected. As successful palliation was defined the ability to tolerate solid food. (TSF).

Results: 178 patients underwent operative treatment. In 57 pts, MBO was the first presentation of the disease; for the others, the median disease-free interval was 16 months. The complication rate was about 42.5% and the postoperative mortality was 16%. The median length of stay was 14 days. 79 pts (44.8%) were discharged from the hospital on a regular diet. 137 pts (76.6%) continued to eat until their last follow-up. Median survival was 90 days. Univariate factors for longer survival were TSF on discharge, colorectal primary and non-metastatic status at first diagnosis. Patients with ascites and whose cancer first presented with MBO had an inferior survival. Non colorectal primary remained a multivariate predictor for decreased survival. TSF was predicted by the absence of ascites, an obstruction not involving the small bowel, and a preoperative albumine of >3.0mg/dl. Multiple logistic regression analysis yielded presence of ascites and small bowel obstruction as predictors of inability to TSF.

Conclusions: Only 35.8% of the patients with MBO from peritoneal carcinomatosis will have prolonged post-operative palliation with significant treatment-related morbidity. TSF at discharge is a useful predictor of continued palliation for most pts. Patients with colorectal cancer may have superior outcome and better palliation; others are at risk for poor outcomes, especially in the presence of ascites and MBO of small bowel. In these pts. is recommended a highly selective use of laparatomy.

924 POSTER

A pilot study of influences on decisions to receive chemotherapy in patients with advanced cancer

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Background: Previous studies have suggested that patients with advanced cancer may find existing survival benefits from chemotherapy inadequate to justify treatment. We wished to test this, and explore contributory factors. Aim To determine what survival advantage justified chemotherapy for patients with advanced cancer and explore influences on decision making.

Methods: Patients with advanced cancer were identified in routine follow-up clinics, and given 4 scenarios describing patients with cancer and expected survival of 4 or 12 months (chosen to approximate the survival without chemotherapy of patients with advanced lung or breast cancer) who were offered either low toxicity outpatient or high toxicity inpatient chemotherapy. They were asked to score on a visual analogue scale (range 0-22 months) what survival benefit they would wish to receive from chemotherapy in each situation, score their quality of life, complete the Beck Hopelessness questionnaire and scored for deprivation category using the Carstairs index.

Results: 31 patients (18 with lung and 13 breast cancer; 12 male, 19 female, median age 64 (range 42-77) years) were given the scenarios. The median survival benefit to justify chemotherapy in each scenario for patients with lung and breast cancer were 7.6 (range 0.1-21.5) and 1.5 (0.4-12.3) months (Mann-Whitney U = 64, p=0.04); 9.7 (0.1-21.6) and 6.0 (0.1-19.5) months (p=0.25); 9.3 (0.2-21.7) and 4.0 (0.3-19.4) months (p=0.1); and 10.3 (0.1-21.8) and 6.0 (0.1-21.5) months (p=0.13). No significant correlation was seen with any factor other than prior experience of chemotherapy. Two way ANOVA of the survival benefits desired showed significant differences between scenarios (p=0.0003) and between patients (p<0.0001). For lung cancer patients 95% of the total variation was patient-related and <1% due to the scenarios, while for patients with breast cancer this was 69% and 7%.

Conclusion: For most patients the survival benefit justifying chemotherapy exceeded that provided by current regimes. However there were wide differences between patients. These were not explained by the factors analysed but were predominantly inter-patient variations independent of clinical scenarios. The criteria for wanting chemotherapy differed between patients with lung and breast cancer.

925 POSTER

An examination into the cultural validity and reliability of the Turkish version of EORTC QLQ-C30

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The assessment of quality of life has become an increasing important aspect to evaluate in cancer clinical trials. One of the most commonly used measures to do this is the European Organization for Treatment and Research of Cancer Quality of Life Questionnaire (EORTC QLQ-C30). While this has been translated into over 48 languages, including Turkish, no large scale cultural psychometric validation of the Turkish translation has been published. We therefore undertook a study to provide evidence of validity and reliability. In a cross sectional study, lung cancer patients were recruited between January and March 2000. All patients were treated and followed in the Departments of Chest Diseases and Radiation Oncology (Izmir/Turkey) were asked to complete the EORTC QLQ-C30. KPS was used to assess the functional status. Patients completed the EORTC QLQ-C30 on the same day with an assessment of the performance status. Two hundred and two patients completed the measure. The mean age was 57.9. When EORTC QLQ-C30 scales were completed, 54,6% of the patients were receiving chemotherapy, 23,2% radiotherapy, and 16% palliative treatments. Psychometric analysis revealed the percentage of missing items were generally low (<1.5%) with the exception of the items related with the global health status (item no 30 and 31, 3.6% missing), financial difficulties (no 28, 3.6% missing) and emotional functioning (no 24, 2.6% missing). All the subscales met the minimal standards of reliability (Cronbach's alpha 0,70). Only role functioning scale differed among the three disease stages of patients (local, locoregional, and metastatic). All interscale correlations were statistically significant (p<0.01). The strongest correlations were found among physical functioning, role functioning, and