they together draw up the assistance program. The professional team is also composed of an internist, a physician for pain therapy, a psychologist, a physiotherapist. Assistance is completely free for the patients and their families. Our home-care model is able to guarantee: best supportive care, antalgic therapy, psychological aid, follow-up. The professional team is also supported by a group of trained volunteers who are responsible for the social aspects of the patients' life.

Results: During these years of activity 311 patients, the mean age was 64.2 yrs (38-90), have been followed: they requested 2087 oncologic visits, 1045 internistic visits, 186 thoracentesis, 180 paracentesis, 1248 nurse interventions, 2260 supportive treatments, 70 physiotherapeutical interventions and 520 psychological supports. During 1244 days of activity we have supplied a total of 7596 services, 6.1 mean/day. The median follow up was 38 days (3-359).

Conclusions: The data regarding our activity showed us that this specifically oriented medical assistance permits education and adaptation of patients and their families with the disease and diminishes the hospitalization of these patients, resulting in an improvement of their quality of life (better preserved in their familiy environment). During our years of activity we have distributed 21.413 days of medical services and it has certainly helped in saving the expenses of the welfare state. So considering the mean cost of a day in general hospital approximately equivalent to 500,00 Euros and considering a day of medical services= a day of non-hospitalization, our work allowed an economical benefit of 10.706.500,00 Euros for the public health resources. Home care models could be the successful instruments and strategies of treatment in advanced cancer care.

917 POSTER

Improvement in quality of life is similar in anaemic patients with solid tumours and lymphoid malignancies treated with epoetin beta

M. Boogaerts. *On behalf of the Epoetin Beta QOL Working Group, Belgium. U.Z. Gasthuisberg, Labo Hematologie Transplant, Leuven, Belgium*

Background: Anaemia related to cancer and its therapy has a profound detrimental effect on the quality of life (QoL) of many patients. Epoetin beta (NeoRecormon®) has been shown to increase haemoglobin (Hb) levels, reduce transfusion needs and ameliorate the symptoms of anaemia in patients with cancer. In this study, we assessed whether the effect of epoetin beta on QoL was comparable in patients with solid tumours and lymphoid malignancies.

Materials and methods: Anaemic patients (Hb $\leq$11 g/dl) with a solid tumour treated with myelosuppressive chemotherapy or haematological malignancy (multiple myeloma, non-Hodgkins lymphoma or chronic lymphocytic leukaemia) were randomised to 12 weeks of open-label treatment with subcutaneous epoetin beta 150 IU/kg three times weekly or control (blood transfusions initiated at guide Hb level of 8.5 g/dl). QoL was assessed using the Short-Form-36 physical component summary (SF-36 PCS) score and the Functional Assessment of Cancer Therapy fatigue and anaemia subscales (FACT-F and FACT-An).

Results: A total of 213 patients were evaluable for QoL assessment after 12 weeks of therapy, of whom 90 had solid tumours (epoetin beta, n=42; control, n=48) and 123 had lymphoid malignancies (epoetin beta, n=62; control, n=61). Median increases in Hb levels were greater with epoetin beta compared with control in patients with solid tumours (2.1 versus 0.9 g/dl) and lymphoid malignancies (1.9 vs 0.9 g/dl). QoL scores for the SF-36 PCS, FACT-F and FACT-An subscales significantly improved with epoetin beta but were either unchanged or had decreased after 12 weeks in the control group both in patients with solid tumours (SF-36 PCS, +3.8 versus 0.8; FACT-F, +3.0 versus +1.0; FACT-An, +1.0 versus 0.0) and lymphoid malignancies (SF-36 PCS, +2.5 versus 1.0; FACT-F, +5.9 versus +0.2; FACT-An, +1.0 versus +1.0). Improvements in QoL with epoetin beta were generally comparable in patients irrespective of tumour type. Overall, changes in SF-36 PCS and FACT-F were correlated with changes in Hb levels ($p<0.05$).

Conclusions: Treatment with epoetin beta is associated with significant improvements in QoL in cancer patients with anaemia irrespective of underlying tumour type.

918 POSTER

The role of patients and doctors in making decisions about the choice of the kind of adjuvant treatment in early breast cancer

A. Jagiello-Gruszfeld[1], E. Szybicka-Flisikowska[1], E. Wachula[1], M. Sikorska[1], A. Kazarnowicz[1], R. Adamowska[1], K. Gugala[2], J. Godlewski[3]. *[1] Regional Cancer Centre, Chemotherapy Department, Olsztyn, Poland; [2] Regional Hospital - Olsztyn, Pathology Department, Olsztyn, Poland; [3] Regional Cancer Centre, Surgery Department, Olsztyn, Poland*

Introduction: Recently adjuvant treatment of breast cancer has become more advisable than the CMF program replaced by antracyclines-containing schemes. There is tendency to make therapeutical decisions by both: the doctor and the patient.

Aim of the Study: We've tried to analyze the criteria of qualifications of patients to different programs of adjuvant treatment, focusing on the role of patient in making therapeutical decision.

Materials and Methods: From June 2002 to March 2003 we treated radically 147 patients with breast cancer. Median age was 53,8 (range: 32-83 yrs). None of the patients had contraindications to use anthracyclines. The stage of the cancer was estimated according to TNM classification from AJCC Cancer Staging Manual from 1997. 86 patients were ER positive, 82 patients PGR positive. Both receptors were negative in 39 cases. Overexpression of HER2/neu was estimated in 92 patients by the immunohistochemical method (test DAKO). Overexpression of HER2/neu (+++) was proved in 21 patients. In 8 patients it was estimated as (++), and in the rest of patients overexpression HER2/neu was not proved. Patients were qualified to adjuvant treatment, between the 2^{nd} and 4^{th} week after radical surgery. In case of 42 women hormonotherapy was the only method of adjuvant treatment. 13 patients with indications for anthracyclines, with metastases to more than 4 lymph nodes were qualified to sequence chemotherapy (4 x ADM/4 x CMF). The remaining 92 patients were carefully examined, 8 of them were treated with CMF program or anthracyclines-containing chemotherapy. All patients with positive receptors ER and PgR received TAM sequentially.

Five physicians were asked to present the order of prognostic factors which are taken into consideration when the decision about the kind of adjuvant treatment was made. Decision was made together with patients in 52 cases (short questionnaire about the criteria of choice of chemotherapy program was used in these cases). In the remaining 40 patients decision about chemotherapy was made by a doctor.

Results: For physicians the most important factor was metastases to axillary lymph nodes, then age of patient, grading (G3) and also the size of breast tumor and preferences of the patients.

For patients the most important factor was the duration of treatment (62% of patients), then the amount of necessary visits during chemotherapy (for 35% women this factor was the most important one), then probability of alopecia (only for 3% of patients this factor was the most important one), probability of other complications and the necessity to take cytotoxic drug orally. 89% patients preferred treatment consisting of 4 courses of AC.

Conclusions: In contemporary oncology it is becoming more important to make therapeutical decisions by both: the doctor and the patient. According to the above analysis of the factors influencing the choice of the kind of adjuvant therapy, some of the factors were emphases in the process of making therapeutical decisions by both a doctor and a patient. The most important factors for patients were duration of chemotherapy and the amount of necessary visits in oncological center.

919 POSTER

Clinically meaningful improvement in disease-related symptoms by gefitinib ('Iressa', ZD1839) in patients with advanced non-small-cell lung cancer: relationship between lung cancer subscale scores and radiographic response and survival

J.-Y. Douillard[1], D. Cella[2], R.B. Natale[3], T.J. Lynch[4], C. Lee[5], D. Carbone[6], A. Kay[7], M. Wolf[7], A. Heyes[8], J. Ward[8]. *[1] CRLCC Rene Gauducheau, Saint-Herblain, France; [2] Evanston Northwestern Healthcare and Northwestern University, Evanston, USA; [3] Cedars-Sinai Comprehensive Cancer Center, Los Angeles, USA; [4] Massachusetts General Hospital, Boston, USA; [5] Fraser Valley Cancer Centre, Surrey, Canada; [6] The Vanderbilt-Ingram Cancer Center, Nashville, USA; [7] AstraZeneca, Wilmington, USA; [8] AstraZeneca, Macclesfield, UK*

Background: Symptom improvement (SI) was a secondary endpoint in a Phase II trial (IDEAL 1) of gefitinib ('Iressa', ZD1839) monotherapy

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

M. Massimino[1], A. Serra[2], P. Navarria[3], F. Spreafico[4], E. Seregni[5], A. Bianchi[6], F. Pallotti[7], M. Terenziani[8], F. Fossati-Bellani[9], L. Gandola[10]. *[1] Istituto Nazionale Tumori, Pediatric Oncology, Milano, Italy; [2] Istituto Nazionale Tumori, Pediatric Oncology, Milano; [3] Istituto Nazionale Tumori, Radiotherapy, Milano; [4] Istituto Nazionale Tumori, Pediatric Oncology, Milano; [5] Istituto Nazionale Tumori, Nuclear Medicine, Milano; [6] Istituto Nazionale Tumori, Pediatric Oncology, Milano; [7] Istituto Nazionale Tumori, Nuclear Medicine, Milano; [8] Istituto Nazionale Tumori, Pediatric Oncology, Milano; [9] Istituto Nazionale Tumori, Pediatric Oncology, Milano; [10] Istituto Nazionale Tumori, Radiotherapy, Milano*

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

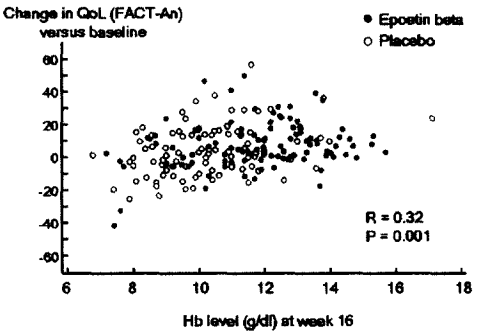
Is there an optimal target hemoglobin level for improved quality of life in cancer-related anemia?

Y. Brandberg, A. Österborg. *Karolinska Hospital, Departments of Oncology and Haematology, Stockholm, Sweden*

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.

M. Krengli[1], M. Sacco[2], G. Loi[1], M. Ronco[3], G. Gambaro[1], A. Cotroneo[2], A. Carriero[2]. *[1] University of Piemonte Orientale, Radiotherapy, Novara, Italy; [2] University of Piemonte Orientale, Radiology, Novara, Italy; [3] Hospital Maggiore della Carità, Pneumology, Novara, Italy*

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.