Median survival was 6 months (95CI 4.1−7.9) with a median progression free survival of 3 months (95CI 2.4−3.6). No differences in survival were encountered.
Conclusions: Cancer incidence and mortality is increased in patients ⩾65 years. Reduced life expectancy, co-morbidities and decreased treatment tolerance due to diminished functional reserve, complicate cancer treatment decision. DTIC is an option as first line systemic therapy in metastatic melanoma. Data on its effectiveness in elderly patients is scarce. Our study shows that DTIC is both tolerable and effective in the elderly as in younger melanoma patients.

4022 POSTER

First Use of Biosimilar Epoetin to Increase Haemoglobin Levels in Patients With Chemotherapy-related Anaemia: a Multicentre Retrospective Clinical Analysis

L.G.M. Kerkhofs[1], G. Boschetti[2], A. Lugini[3], D.L. Stanculeanu[4]. [1]*Admiraal de Ruyter Hospital, Vlissingen, The Netherlands;* [2]*Hôpital Edouard Herriot, Lyon, France;* [3]*Ospedale San Camillo de Lellis, Rieti, Italy;* [4]*Bucharest Institute of Oncology, Bucharest, Romania*

Background: Biosimilar epoetin (Binocrit®) has been approved in Europe on the basis of comparable efficacy, safety and quality with its epoetin alfa reference product and is now in clinical use for the treatment of chemotherapy-induced anaemia. This retrospective multicentre clinical audit is the first report of biosimilar epoetin in clinical practice.
Methods: Data from patients with solid tumours and chemotherapy-induced anaemia treated with biosimilar epoetin were collected at 4 European centres (in France, Italy, the Netherlands and Romania). Haemoglobin (Hb) levels were recorded at regular intervals during therapy for up to 26 weeks. Hb response rates with and without intravenous (IV) iron were evaluated. Hb response was defined as (A): Hb increase ⩾1 g/dl in 4 weeks or Hb 10−12 g/dl during study or (B) Hb increase ⩾1 g/dl in 4 weeks or ⩾2 g/dl during study). Safety findings were also recorded.
Results: A total of 93 patients were included with a mean age of 63±11 years. Most frequent tumour types were breast (19%), lung (16%), colon (16%) and pancreatic (14%) cancers. Nine percent of patients received red blood cell transfusions and 27% received iron (68% IV, 32% oral). Initial dose of once weekly biosimilar epoetin was 30000 IU in 25% and 40000 IU in 71% of patients (4% not known). Mean± SD Hb at initiation of biosimilar epoetin therapy was 9.9±0.7 g/dl and mean ± SD maximum Hb level achieved was 11.2±2.1 g/dl. Response rate overall was 78% of patients (response definition A) or 54% of patients (response definition B). Using response definition A, response rates were similar in patients irrespective of whether they received IV iron or not (76% with IV iron vs 78% without). However, using response definition B, use of IV iron resulted in a higher response rate (71% with IV iron vs 50% without). No unexpected safety findings were reported.
Conclusion: Biosimilar epoetin is safe and effective for the treatment of chemotherapy-induced anaemia in patients with solid tumours. Use of biosimilars may provide important cost-savings in the supportive care of patients with cancer.

4023 POSTER

First-line Oral Vinorelbine for Elderly or Unfit Patients With Advanced/metastatic Non-small Cell Lung Cancer

G. Mansueto[1], F. Longo[2], L. Stumbo[2], L. De Filippis[2], E. Del Signore[2], S. Quadrini[1], G. Del Bene[2], D. Adua[2], V. Lapadula[2], M. Di Seri[2]. [1]*Fabrizio Spaziani Hospital, Medical Oncology, Frosinone, Italy;* [2]*Policlinico Umberto I, Medical Oncology, Roma, Italy*

Background: Available data support the use of single agent chemotherapy in elderly or unfit patients (pts) with non-small cell lung cancer (NSCLC). Among the third generation chemotherapy agents, vinorelbine (VNB) has demonstrated its efficacy and symptomatic benefit in this population of pts. We investigated efficacy and safety of oral VNB as first-line treatment in pts with stage III/IV NSCLC not suitable for a standard doublet chemotherapy.
Methods: 38 consecutive elderly (>70 years) or unfit patients with advanced/metastatic NSCLC were treated at two institutions: median age was 78.1 years (range 71−84), ECOG PS 0/1/2=1/24/13 pts, stage IIIB/IV=17/21. Histology was: adenocarcinoma 44.7%, squamous 42.1%, other/NOS 13.2%. All pts received oral VNB 60 mg/m^2 day 1, 8 q until progression or unacceptable toxicity. Time to progression (TTP) was the primary endpoint. Response evaluation was made according to RECIST criteria.
Results: Mean of cycles administered per patient was 9.3 (354 cycles totally). A partial response (PR) was observed in 5.2% of pts and a stable disease (SD) lasting ⩾ 6 months in 42.1% of pts for an overall clinical benefit rate (CBR) of 47.3%. Median time to progression (TTP) was 7.8 months. Very few pts reported G3 adverse events (neutropenia and anemia, 2.6%), as the most reported toxicities were low-moderate grade. No dose reduction was required.
Conclusions: In our experience, oral VNB seems to be an option for elderly, unfit pts with metastatic NSCLC not suitable for first-line combination chemotherapy. Oral formulation allows a good compliance to chemotherapy, reduces costs for treatment and adverse events management and finally helps patients' quality of life. Treatment was very well tolerated, with any need for dose adjustment. Updated results on survival will be presented at the meeting.

4024 POSTER

Customized Chemotherapy on the Basis of EGFR Mutation Status for Elderly Patients With Advanced Non-Small-Cell Lung Cancer

K. Kunimasa[1], N. Katakami[2], K. Masago[3], H. Yoshioka[1], K. Tomii[4], T. Kaneda[5], M. Hirabayashi[6], T. Morizane[7], S. Fujita[2], T. Mio[3]. [1]*Kurashiki Central Hospital, Respiratory Medicine, Kurashiki, Japan;* [2]*Institute of Biomedical Research and Innovation Hospital, Integrated Oncology, Kobe, Japan;* [3]*Kyoto University Hospital, Respiratory Medicine, Kyoto, Japan;* [4]*Kobe City Medical Center General Hospital, Respiratory Medicine, Kobe, Japan;* [5]*Kobe City Medical Center West Hospital, Respiratory Medicine, Kobe, Japan;* [6]*Hyogo Prefectural Amagasaki Hospital, Respiratory Medicine, Amagasaki, Japan;* [7]*Kanagawa Dental College, Internal Medicine, Kanagawa, Japan*

Background: Elderly patients are more vulnerable to toxicity from chemotherapy, possibly due to progressive organ failure and comorbidities. Activating epidermal growth factor receptor (EGFR) mutations in non-small-cell lung cancer (NSCLC) are associated with enhanced response to EGFR tyrosine-kinase inhibitors. We studied patients with advanced NSCLC where treatment was customized based on EGFR mutation status. We report the final survival analysis from the trial.
Patients and Methods: We screened 57 chemotherapy-naïve patients with histologically or cytologically confirmed NSCLC, stage IIIB or IV, age 70 or older, and with a performance status 0 or 1, for the EGFR exon 19 codon 746–750 deletion and exon 21 L858R mutation. Twenty-two patients with EGFR mutations received gefitinib (250 mg/day); 32 patients without mutations received vinorelbine (25 mg/m^2 Days 1 and 8, every 21 days) or gemcitabine (1000 mg/m^2 Days 1 and 8, every 21 days). The primary endpoint was response rate. The trial has been registered at UMIN-CTR (www.umin.ac.jp/ctr/index/htm), registration identification number C000000436.
Results: Response rate was 45.5% (95% CI: 24.4%, 67.8%) in patients with EGFR mutations and 18.8% (95% CI: 7.2%, 36.4%) in patients without EGFR mutations. Median overall survival was 27.9 months (95% CI: 24.4 months, undeterminable months) in patients with EGFR mutations and 14.9 months (95% CI: 11.0 months, 22.4 months) in patients without EGFR mutations. In the gefitinib group, grade 3/4 hepatic dysfunction occurred in 23% and grade 3/4 dermatitis in 5% of patients. In patients treated with vinorelbine or gemcitabine, the most common grade 3/4 adverse events were neutropenia (47%; four had febrile neutropenia), anemia (13%), and anorexia (9%). No treatment-related deaths occurred.
Conclusions: Treatment customization based on EGFR mutation status deserves consideration, especially for elderly patients who often cannot receive second-line chemotherapy due to poor organ function or comorbidities.

4025 POSTER

Supportive Treatment of Chemotherapy-Induced Neutropenia With Biosimilar Filgrastim: the HEXAFIL Non-Interventional Study

H. Tesch[1], M. Indorf[2], T. Schaller-Kranz[3]. [1]*Onkologie Bethanien, Onkologische Gemeinschaftspraxis, Frankfurt, Germany;* [2]*iOMEDICO AG, Freiburg, Germany;* [3]*Hexal AG, Holzkirchen, Germany*

Background: Granulocyte-colony stimulating factors are frequently used to prevent or treat chemotherapy-induced neutropenia (CIN) in patients with cancer. Biosimilars of filgrastim have recently become available in Europe. A non-interventional observational study on the use of biosimilar filgrastim (Filgrastim Hexal®) was conducted to provide further insight into its therapeutic efficacy and routine clinical use in Germany.
Methods: A total of 500 adult patients with cancer receiving chemotherapy (CT) and biosimilar filgrastim who signed informed consent were enrolled at 100 study centers. Patients received biosimilar filgrastim either for primary prophylaxis (PP) of neutropenia, or as secondary prophylaxis (SP) or treatment (TX), i.e. after having experienced neutropenic complications in the first documented CT cycle.
Results: To date (4/2011), data have been reported for 343 patients, with data from three consecutive CT cycles available for 242 patients.

Of these, 231 patients showed normal leukocyte values at start of CT (118 PP and 113 SP/TX patients). Median treatment duration was 4 days and was comparable across all three CT cycles. PP was associated with longer administration of filgrastim compared with SP/TX (5 vs 3 days). Increased duration of filgrastim administration was also seen in patients with co-morbidities (5 vs 4 days in patients without concomitant disease). In patients receiving filgrastim for PP, leukopenia was prevented over three cycles of CT in 48%, while 24% and 10% had leukopenia CTC grade 3 and 4, respectively. In comparison, severe leukopenia was observed in 54% (CTC grade 3) and 12% (CTC grade 4) of the patients receiving filgrastim as SP/TX; prevention of leukopenia was possible in only 14% of SP/TX patients. Nine percent of PP patients and 14% of SP/TX patients experienced neutropenic complications and/or febrile neutropenia. CT was discontinued during the first CT cycle in 3% of PP and 9% of SP/TX patients. According to the assessment of the attending physician, 96% of patients benefited from receiving filgrastim.
Conclusions: PP with biosimilar filgrastim was more effective at preventing CIN than SP or TX. Early prophylactic use of filgrastim therapy in the course of treatment is beneficial to patients. Cost savings associated with biosimilar filgrastim may improve patient access to therapy and encourage a move towards increased primary prophylactic use.

4026 POSTER

Rate of Hemoglobin (Hb) Decline by Age and Tumour Type in Patients (pts) Receiving Chemotherapy (CT) Without an Erythropoiesis-stimulating Agent (ESA) in the United States Community Setting

M. Pirolli[1], H. Collins[2], J. Quigley[1], S. Hulnick[1]. [1]*SDI, Oncology Data Services, Plymouth Meeting PA, USA;* [2]*Amgen Inc., Hematology/Oncology, Thousand Oaks CA, USA*

Background: CT often induces anemia that can be treated with transfusions or ESAs (the ESA labels state to initiate ESAs in CT pts at Hb ⩽10 g/dL [EU] or <10 g/dL [US]); since low Hb of <9 g/dL may increase transfusions, understanding how quickly Hb declines from <10 to <9 g/dL in CT pts may help optimize ESA use.
Material and Methods: This retrospective observational assessment used clinic-based EMR data to estimate the proportion of CT episodes in which Hb declined from <10 to <9 g/dL by 3, 6, and 9 weeks (wks). Episodes with taxane, platinum, anthracycline, or gemcitabine doublets were identified at the time of 10 ⩽ Hb < 11 g/dL and when Hb further declined to <10 g/dL at least once in 9 wks. Episodes were re-indexed at Hb <10 g/dL to estimate the proportion that further declined to Hb <9 g/dL by 3, 6, and 9 wks without ESAs. Data were stratified by tumour type and age (<65 vs ⩾65 years [yrs]).
Results: 10942 CT episodes (between 8/1/08 and 6/24/10) with 10 ⩽ Hb < 11 g/dL were identified in 10523 pts from 63 US community oncology practices. Episodes evaluated included 72% women; 39% of the sample was ⩾65 yrs. 5535 episodes (51%) declined from baseline 10 ⩽ Hb < 11 g/dL to Hb <10 g/dL by 9 wks. Estimates of the proportion of these episodes that declined from Hb <10 to <9 g/dL for each tumour type by age category are shown (Table). Compared with pts <65 yrs, a statistically significantly higher proportion of episodes for pts ⩾65 yrs declined to Hb <9 g/dL within 3 wks (38% vs 34%; p = 0.0026) and 9 wks (49% vs 43%; p = <0.0001). A similar result was seen in breast cancer pts (<65 vs ⩾65 yrs) at 3 wks (p = 0.05) and 9 wks (p = 0.02).

Table: Proportion of CT episodes with Hb decline from <10 to <9 g/dL analyzed by tumour type and age categories (yrs).

	3 wks	6 wks	9 wks
Total episodes (n = 5535)	35%	43%	46%
⩾65 (n = 2222)	38%	46%	49%
<65 (n = 3313)	34%	40%	43%
Breast (n = 2110)	28%	35%	38%
⩾65 (n = 473)	31%	40%	42%
<65 (n = 1637)	27%	33%	36%
Lung (n = 1804)	42%	48%	51%
⩾65 (n = 1023)	41%	47%	51%
<65 (n = 781)	43%	50%	53%
Ovarian (n = 453)	36%	43%	48%
⩾65 (n = 199)	40%	48%	51%
<65 (n = 254)	32%	40%	46%
Other (n = 1168)	40%	47%	50%

Conclusions: Results suggest that pts with various tumour types receiving CT without ESAs transition quickly from Hb <10 to <9 g/dL. The proportion of CT episodes declining to <9 g/dL was higher in pts ⩾65 yrs than in younger pts. As elderly pts are less likely to tolerate low Hb due to co-morbidities, awareness of the higher risk of Hb decline in these pts is important for anemia care.

4027 POSTER

Age-related Changes in Plasma Levels of Inflamatory and Angiogenic Cytokines in Patients With Cancer

J. Spano[1], P. Chaibi[2], S. Vignot[1], J.C. Thery[1], T. De La Motte Rouge[1], M. Gil-Delgado[1], D. Khayat[1], R. Mouawad[1]. [1]*CHU Pitié Salpetrière, Medical Oncology, Paris, France;* [2]*Charles Foix Hospital, Geriatric Department, Ivry sur Seine, France*

Background: The majority of cancer incidence and mortality occurs in individuals aged older than 65 years, and the number of older adults with cancer is projected to significantly increase. As such, understanding the changes accompanying age in the context of the cancer patient is of critical importance. Age-related changes can impact tolerance of anticancer therapy and can shift the overall risk-benefit ratio of such treatment. It is increasingly recognized that several laboratory markers may predict morbidity and mortality in older adults; these biologic variables may further help in stratifying this group of patients based on risk. In this study we examine inflammatory and angiogenic markers in cancer patients classified according to their age in older adults.
Methods: Using ELISA test circulating Il-6, TNF alpha and VEGF were measured in the sera of 80 patients with different cancer of whom 38 (48%) were female in comparison to 40 healthy controls. Three groups of patients were studied, the first consisted of 25 patients (age 30−40 years); the second of 25 (age 40−70 years), the third group of 30 elderly patients (>70 years).
Results: Serum IL-6, TNF alpha and VEGF levels were higher in cancer patients as compared to control group. When patients were classified according to their age, a significant age-related increase of IL-6 and VEGF were observed (p = 0.009 and 0.034 respectively) but not with TNF alpha. Furthermore, high IL-6 and VEGF level were associated with further functional adverse outcomes.
Conclusions: A specific inflamatory and angiogenic status exist for elderly patients. The increased level of these markers might predispose these patients to clinical manifestations and non tolerence of the treatment. However, a study comparing these parameters only in elderly patients (>70 years) and relation to their clinical status are necessary to confirm these results.

4028 POSTER

Ability of the Comprehensive Geriatric Assessment to Predict Frailty in Elderly Patients Diagnosed With Cancer in a General Hospital

M. Molina-Garrido[1], C. Guillén-Ponce[2]. [1]*Virgen de la Luz Hospital, Medical Oncology, Cuenca, Spain;* [2]*Ramón y Cajal Hospital, Medical Oncology, Madrid, Spain*

Introduction: They have been developed different criteria for defining frailty in the elderly, but they are not unanimous, especially in the field of Oncogeriatry. Linda Fried's criteria are the most accepted in the scientific literature in general, however, the Oncogeriatry has made special emphasis on considering the Comprehensive Geriatric Assessment (CGA) as the main tool for distinguishing between frail and not frail patients.
Objectives: The aim of this study was to determine the role of CGA to predict the risk of frailty in elderly patients.
Material and Methods: It was conducted a prospective study in the Unit of Cancer in the Elderly, Section of Medical Oncology, in the General Hospital Virgen de la Luz de Cuenca. They were collected the following data: patients' age, sex, kind of tumour, tumoral stage, self-perceived health status and CGA. It was used the CGA model created by MJ Molina-Garrido et al. By a bivariate logistic regression analysis it was analyzed which of these factors are associated with risk of frailty, as measured by the Barber questionnaire.
Results: We included a total of 204 patients with a mean age of 79.2 years (range: 70.2 to 96.2 years). 57.4% (n = 117) were men. 30% had ECOG 0 (n = 61). 61.5% (n = 115) could read and write. 81.2% of the elderly (n = 134) considered that their health status was equal to or better that the health status for an individual of its own age. The most common tumours were digestive tumours (39.7%, n = 81), breast cancer or gynecological tumours (25.0%, n = 51) and urological and prostate tumours (14.7%, n = 30). 41.2% of patients (n = 80) had metastatic tumours. 74.7% (n = 148) had risk of frailty by measured by the Barber questionnaire.
In the bivariate analysis, only age (OR 1.161, 95% CI 1.034 to 1.303, p 0.011) and dependency in IADL (instrumental activities of daily live) (OR 18.149, 95% CI 2.663 to 123.713, p 0.003), were associated with a higher risk of frailty. The model had a Nagelkerke R2 value of 0.337. The