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

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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

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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

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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

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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.