Results: Sixty pts were eligible (median age 82 years, range 71−95); pts' characteristics are outlined in Table I. MGA was done in 42 pts. More than half pts were evaluated as frail. After 6 months of treatment, 53 pts (88.3%) had either clinical or radiological objective response. After a median treatment time of 16.2 months, surgery was performed in 5 pts; surgery was not done either because not proposed (31 pts), or refused (13 pts) or not indicated by surgeon (11 pts). Adverse events were reported in 36 pts: arthralgias (*43.3%*), gastrointestinal side effects (*11.7%*), hot flashes, memory disorders and headaches (*6.7%*). At median follow-up of 35.1 months, 48 pts (80%) are alive and 10 pts (16.7%) have relapsed. OS and PFS at 3 years were 80.7% and 89.8%, respectively, with median time to first progression of 5.9 years. No statistical difference was observed for PFS between fit and unfit pts and between pts with grade 3−4 comorbidity vs pts with none, whereas a trend towards worse PFS was observed for pts who had side effects vs those who had not. OS was worse for frail vs fit pts ($p = 0.07$), and was significantly worse for Her2-positive vs Her2-negative pts ($p = 0.05$); a trend for poorer survival was observed for pts with grade 3−4 comorbidity, whereas no difference was seen for pts who had side effects vs those who had not.

Conclusion: Most of the pts who were started on neoadjuvant endocrine treatment did not undergo further surgery. Local relapse was observed in about 10% of pts; worse PFS for pts who had side effects could be influenced by higher discontinuation rate. Median OS has not been reached, despite surgery was omitted in most of the pts. For frail pts, definitive endocrine treatment is an alternative option to surgery.

Table I: Pts' characteristics

		N (%)
Tumour size	cT2	24 *(40.0)*
	cT3	7 *(11.7)*
	cT4	29 *(48.3)*
Lymphnodes	Positive	23 *(38.3)*
	Negative	10 *(16.7)*
	Unknown	27 *(45.0)*
Hormone receptors	Positive	56 *(89.0)*
	Unknown	7 *(11.0)*
Ki67	<5%	8 *(13.3)*
	5−20%	28 *(46.7)*
	>20%	16 *(26.7)*
	Unknown	8 *(13.3)*
Her2 status	Positive	5 *(8.3)*
	Negative	35 *(58.3)*
	Unknown	20 *(33.4)*
Grade	G1−2	25 *(40.6)*
	G3	9 *(15.0)*
	Unknown	26 *(43.3)*
MGA	Fit	11*(18.3)*
	Vulnerable	15 *(25.0)*
	Frail	34 *(56.7)*
ADL	Independent	16 *(26.7)*
	Dependent	26 *(43.3)*
	Unknown	18 *(30.0)*
IADL	Independent	29 *(48.3)*
	Dependent	13 *(21.7)*
	Unknown	18 *(30.0)*
Comorbidity	G3-G4	26 *(43.3)*
	All grade	60 *(100)*
Treatment type	Exemestane	26 *(43.3)*
	Letrozole	26 *(43.3)*
	Anastrozole	8 *(13.4)*

*Activities of Daily Living; **Instrumental Activities of Daily Living.

4020 POSTER

Efficacy and Toxicity of Adjuvant FOLFOX Chemotherapy in Elderly Patients With Stage III Colon Cancer − Single Center Study

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Background: Elderly patients derive similar benefit from 5-FU based adjuvant chemotherapy in stage III colon cancer. However, conflicting data exist regarding additional benefit from Oxaliplatin, fluorouracil, and leucovorin (FOLFOX) chemotherapy in elderly patients and there are scarce data on the efficacy of adjuvant chemotherapy in elderly population in Asian countries.

Methods: Single center, retrospective analysis was performed to compare the safety and efficacy of adjuvant FOLFOX-4 chemotherapy, in elderly (⩾ 65 yrs) vs younger patients with stage III colon cancer after R0 surgical resection. Endpoints included grade 3, 4 toxicities, 3 year disease free survival rate and dose intensities.

Results: Using prospectively maintained cancer registry, 1221 patients were identified to have received surgery for colon cancer from May 2003 − March 2010 in Seoul National University Bundang Hospital (stage I: 213, stage II: 371, stage III: 391, stage IV: 246). Out of 391 patients with stage III colon cancer, more patients in the elderly group were treated with capecitabine (34.5% vs 7.7%) or received no adjuvant chemotherapy (14.7% vs 6.6%). Total of 229 patients received adjuvant FOLFOX chemotherapy and were included in the analysis; 87 (62%) ⩾ 65 yrs vs 142 (75%) <65 yrs. The median number of cycles of chemotherapy received was 11.0 (⩾ 65 yrs) vs 11.5 (<65 yrs, $P = 0.57$), and percentage of patients who received the planned 12 cycles were 81.6% (⩾ 65 yrs) vs 89.4% (<65 yrs). Elderly patients had similar clinical and pathologic characteristics as younger patients in terms of T and N stage, histologic types, MSI status, ECOG PS and BMI, but more patients had Charlson's co-morbidity score of >2 (41.4% vs 16.2%, $p < 0.05$) in the elderly. Estimated 3 yr DFS rate was 74.9% vs 74.8% ($p = 0.713$), and 3 yr OS rate was 93.7% vs 93.9% ($p = 0.868$) in the ⩾65 vs <65 years age group. There were no significant differences in the occurrence of grade 3−4 anemia, thrombocytopenia, nausea, vomiting, diarrhea and neuropathy. Grade 3−4 neutropenia was the only toxicity that showed higher frequency in the elderly (62.1% vs 46.5%, $p = 0.022$). Elderly patients received less relative dose intensity of oxaliplatin (0.757 vs 0.788) and 5-FU (0.746 vs 0.795).

Conclusions: Elderly patients showed similar efficacy without significant increase in toxicity from adjuvant FOLFOX chemotherapy in curatively resected stage III colon cancer in Korean patients.

	Elderly patients (N = 87)	Young patients (N = 142)	P-value
Neuropathy (>Gr2)	25 (28.7%)	28 (19.7%)	0.116
Neutropenia (Gr3−4)	54 (62.1%)	66 (46.5%)	0.022
Emesis (Gr3−4)	1 (1.1%)	0	0.163
Diarrhea (Gr3−4)	6 (6.9%)	6 (4.2%)	0.379
Infection	5 (5.7%)	4 (2.8%)	0.269
Hospitalization	1 (1.1%)	1 (0.7%)	0.729

4021 POSTER

Dacarbazine as First Line Treatment of Metastatic Melanoma in Elderly Patients

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Background: Incidence and mortality of melanoma is increasing worldwide. As population ages, more elderly patients are diagnosed with melanoma. Dacarbazine (DTIC) is used as 1st line agent with response rates of 10−20% and median overall survival of 6 months. Older patients are generally underrepresented in cancer clinical trials. Our purpose was to assess the comparative effectiveness of dacarbazine as 1st line treatment of metastatic melanoma in elderly versus younger pts.

Materials and Methods: Retrospective cohort study, in a Portuguese cancer centre, of metastatic melanoma patients treated with DTIC as 1st line systemic treatment. A cutoff of ⩾ 65 years was used to define elderly patients. Toxicity was evaluated using common terminology criteria for adverse events (CTCAE), version 3, and efficacy through Kaplan–Meier's method. Differences in demographics, baseline status, treatment delivery and toxicity between age groups were compared with parametric and non-parametric tests as appropriate. Log rank test was used to compare efficacy across groups.

Results: Between 2005 and 2009, 109 metastatic melanoma patients were treated with DTIC. Median age was 58 years (39% ⩾65; 18% ⩾70). Baseline characteristics of the two age groups were comparable in gender, ECOG status and pattern of metastases. DTIC median relative dose intensity was 99% and median number of DTIC cycles was 4, similar in both age groups. Toxicity profile of DTIC was similar between groups: global severe adverse event (SAE) rate was 19%; most common SAEs were myelosuppression (17%) and asthenia (2%). Two deaths occurred on treatment due to undetermined causes, both in patients <65 years. Main reason for treatment discontinuation was disease progression (68%).

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.