Results: 119 patients were recruited (Nov ’11–May ’12). Eighty-one patients were ≤ 70 yrs (median 63 yrs) and 38 patients were > 70 yrs (median 76 yrs). The two age groups had similar cancer stage (advanced: Stage IIIA or above): 81.4% (≤ 70 yrs) vs 76.3% (> 70 yrs), p = 0.51, histology (NSCLC): 73% (≤ 70 yrs) vs 82% (> 70 yrs), p = 0.30, treatment (on chemotherapy): 64% (≤ 70 yrs) vs 76% (> 70 yrs), p = 0.19, smoking status: ex-smokers: 79% (≤ 70 yrs) vs 60% (≥ 70 yrs) and current 13% (> 70 yrs) vs 31% (≤ 70 yrs), p = 1.00. However, age did influence pack year history: median 30.00 (≥ 70 yrs) vs 40.00 (≤ 70 yrs), p = 0.04. The median MCLCS score (range 1–50) was 23 (≤ 70 yrs) vs 22 (> 70 yrs), p = 0.52, VAS score 39 mm (≤ 70 yrs) vs 46 mm (> 70 yrs), p = 0.83. Item 31 responses did not differ significantly among age groups: not at all: 1%, a little: 33%, quite a bit: 46%, and very much: 20% (≤ 70 yrs), vs. 3%, 33%, 50% and 20% respectively (> 70 yrs), p = 1.00. The CTCAE score was 1: 64%, 2: 36% (≤ 70 yrs) vs. 1: 49%, 2: 51% (> 70 yrs), p = 0.12. In younger patients, item 31, VAS and MCLCS scores were all highly correlated (range: r = 0.71–0.74, all p < 0.05: Spearman’s) whilst the correlations were low when they were compared to the CTCAE score (r = 0.47–0.48, all p < 0.05 Spearman’s). In older patients, item 31, the VAS and the MCLCS were also highly correlated (r = 0.69–0.83, all p < 0.05: Spearman’s) but the correlations between the CTCAE grading and the other tools were lower (r = 0.50–0.67, all p < 0.05: Spearman’s). Age group did not influence the relationship between item 31 and MCLCS score (p-value 0.17), item 31 and VAS score (p-value 0.77), nor item 31 and CTCAE score (p-value 0.79).

Conclusions: This study suggests that cough severity and cough-related QoL do not differ significantly in LC patient above and below 70 years of age. Furthermore, the VAS, item 31 and MCLCS all perform well in younger and older patients. Therefore, they are valid for use in elderly patients. However, the CTCAE is a blunt instrument that poorly discriminates cough severity. A fuller analysis is planned on completion of recruitment (target = 180). Data relating to CLiC study has been submitted in abstract form and planned poster presentation at the EORTC QoL conference 2012 but this does not include age group analysis.

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Darbepoetin Alfa in older patients with chemotherapy induced anaemia: Is the recommended initial dose optimal for elderly? T. Landre, C. Taleb, R. Ratiney, H.P. Cornu, G. des Guetz, G. Sebbane. Oncogeriatrique Coordination Unit (UCOG 93), Hôpitaux Universitaires de Paris Seine St Denis, APHP, France

Darbepoetin Alfa (DA) is used as treatment of symptomatic chemotherapy induced anaemia (CIA) in cancer patients. The recommended initial dose is 500 μg (6.75 μg/kg) given once every three weeks, or once weekly dosing can be given at 2.25 μg/kg body weight. However, there is no specific data on DA use in elderly individuals > 75 years.

Purpose of the study: To evaluate DA once weekly treatment of anaemia in geriatric cancer patients > 75 years receiving chemotherapy.

Methods: The study was carried out at Rene Muret Geriatric University Hospital (550 beds). A retrospective review of medical records was performed for patients treated with DA 150 μg between June 2011 and July 2012. Demographics, primary tumour type localization, Performance Status, Hb levels at baseline, after 1 week and after 2 weeks, thromboembolic events and red blood cell transfusions requirement were also evaluated.

Results: 10 patients (7 females), mean age 82 years [77–88] evaluated.

4 were treated for gastrointestinal tumour, 4 for Non Hodgkin Lymphomas, 1 for Breast cancer and 1 for Multiple Myeloma. Performance status was 2 in 6 patients and 3 in 4 patients. DA 150 μg was administered by the subcutaneous route to patients with CIA (baseline Hb concentration ≤ 10 g/dL).

Mean Hb level was 11.46 g/dL +/- 0.88 after 1 week and was 12.29 g/dL +/- 1.03 after 2 weeks. Recommended target Hb level (12 g/dL) was reached by 8 (80%) patients.

From baseline to first measurement, DA therapy increased Hb by 2.12 g/dL +/- 1.14.

No thromboembolic events were observed. Red blood cell transfusions were required for 2 patients.

Conclusions: DA 150 μg appears effective for treatment of CIA in older patients. However, the rise in Hb is ≥ 2 g/dL in one week. This excessive increase maybe due to reduced chemotherapy doses, fewer numbers of chemotherapy cycles and lower body weight in older population. When correcting anaemia in older cancer patients one should also consider that erythropoietin stimulating agents may stimulate cancer growth and cause thrombosis. In consequence DA dose reduction should be early considered in geriatric patients. More early and step by step correction of haemoglobin levels may be useful in patients > 75 years of age.

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Efficacy and safety of lipogafilgrastim in elderly patients with non-small-cell lung cancer receiving cisplatin/etoposide chemotherapy C. Volovat1, I.M. Bondarenk2, D.A. Gladkov3, R. Elaesser4, A. Buchner4, P. Bias4, U. Mueller5, 1Centrul de Oncologie Medicala, Iasi, Romania, 2Dnipropetrovsk State Medical Academy, Dnipropetrovsk, Ukraine, 3Chebybinsk Regional Clinical Oncology Center, Chebybinsk, Russia, 4Teva ratiopharm, Ulm, Germany, 5Teva Pharmaceuticals, Inc., Ulm, Germany

Purpose of the Study: The efficacy and safety of lipogafilgrastim, a glycosylated and pegylated recombinant granulocyte-colony stimulating factor (G-CSF) for reducing febrile neutropenia (FN) rates in patients receiving cisplatin/etoposide for stage IIIb/IV non-small-cell lung cancer, has been shown to be in line with published results for filgrastim and pegfilgrastim therapies. However, patients aged > 65 years are at a higher risk of developing FN vs the majority. This post hoc analysis was performed to compare outcomes in elderly patients (≥ 65 years) with younger patients treated with lipogafilgrastim vs pegfilgrastim.

Methods: In this double-blind, randomized, placebo-controlled study, 375 patients with ≥ 1.5 x 10^9 neutrophils/L and ≥ 100 x 10^9 platelets/L were randomly assigned to lipogafilgrastim 6 mg (n = 250) or placebo (n = 125). The number of patients who were > 65 years of age in either group was comparable (n=53 [21.2%] and n=30 [24.0%], respectively). Study medication was injected subcutaneously on Day 4 of the chemotherapy cycle. The primary efficacy endpoint was the incidence of FN during cycle 1. Odds ratios (OR), exact 95% confidence intervals (CI), and asymptotic chi-squared P-values of FN in the lipogafilgrastim 6 mg vs placebo in either age group were calculated.

Results: During cycle 1, fewer elderly patients (> 65 years) receiving lipogafilgrastim 6 mg (0.53 [0.00%]) vs placebo (4/30 [13.33%]) had FN (OR [95% CI] = 0.0 [0.0000–0.8105]; P = 0.0064). As would be expected, rates of FN dropped significantly in subsequent cycles of chemotherapy. There did not appear to be any significant difference in incidence severity or type of adverse events experienced within treatment groups by age group.

Conclusions: This analysis suggests that lipogafilgrastim treatment is associated with reduced FN risk vs placebo in elderly patients receiving cisplatin/etoposide for stage IIIb/IV non-small-cell lung cancer, a population that is at an elevated risk of developing FN compared with younger patients.
References
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P124 Microbiology and management of malignant breast cancer wounds in geriatric oncology
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Purpose of the Study: The management of malignant wounds is a challenge for the supportive care team. Patients have an impaired quality of life due to the presence of the skin lesion. The discomfort related to odour, pain, risk of infection and bleeding is frequently observed in this type of wound. The goal of the wound care (curative or palliative) depends on the patient’s response to anticancer treatments and the surgical possibilities, sometimes limited in geriatric oncology. The odours due to necrosis and microbial flora especially impact the distress for patients, families and caregivers.

Objectives: The objectives of this study are to investigate the bacterial profile of malignant breast cancer wounds and suggest the most appropriate approach to manage two important symptoms: the odours and the risk of infection.

Methods: Followed case studies of malignant wounds of older patients and compared the clinical aspect and impact with the results of the bacterial flora.

Results and Discussion: Many antimicrobial products and antibiotics are proposed to reduce the growth of bacteria and the odours, but there is no evidence of their efficiencies (except metronidazole), and potential adverse effects. Only very few studies exist.

In our experience, the malignant wounds were colonised by multiple bacterial species and the most common resident were Staphylococcus aureus and Pseudomonas aeruginosa. The anaerobic bacteria were present in many cases (e.g.: Peptostreptococcus, Fusobacterium necrophorum). The odours seem dependent of: the number of bacteria, the presence of anaerobic germs and special bacteria like Proteus mirabilis or Peptostreptococcus. Antimicrobial dressings seemed to be inefficient and charcoal dressing completely controls odours in only 50% of cases.

Conclusions: Contrary to other chronic wounds, malignant wounds are under the influence of the progression of the cancer and the effects of the treatments (e.g.: chemotherapy/aplasia). Our findings suggest that planktonic bacteria, biofilm, and bacterial volatiles interact in dynamic context. No one dressing could control odours and colonisation, so it is necessary to know, use and adapt all the products and wound care to each situation, in order to limit the prescription of antibiotics. Moreover, peculiarities of this elderly population must be considered: frequency of dressings, inpatient or outpatient, comorbidities, and personal hygiene. A multidisciplinary cooperation between the geriatrician, the oncologist and the nurses is essential.

Background and Aims: Screening older cancer patients for supportive care needs is recommended but currently not routine practice. Community-based aged care and carer support agencies are also not utilised routinely. We employed a self-filled geriatric assessment (GA) questionnaire in all patients over 70 yo at initial presentation to our cancer clinic in regional Australia. Guided intervention ensued using a dedicated cancer care coordinator (CCC). The aim of the project was to assess feasibility and map referral pathways for supportive care with existing, community-funded aged care services being key referral destinations.

Methods: The self-filled, multidimensional geriatric assessment (GA) questionnaire developed by the Royal Adelaide Hospital was adapted to suit local needs. Domains included are comorbidities, activities of daily living (ADLs), memory, geriatric syndromes, a distress thermometer, pain score and level of social supports. This GA was sent to all patients over 70 yo before initial presentation to the oncology clinic. The GA was scored by a CCC who then contacted the patient (and carer) by telephone and referred them to support services as required. The tool was readministered at 6 weeks and 6 months.

Results: From 28/3/2011 to 7/2/2012, 155 baseline screens occurred. All patients were outpatients. Median age 78 yrs (range 70–95). Male/Female = 93/62. Patients with comorbidities (self-reported) = 50%, including memory issues (17%) and falls (20%). Pain reported by 42% and distress by 45% of patients. Up to 45 patients reported at least one problem with ADLs (28%). Total number of supportive care referrals = 73. Key referral destinations were community aged care assessment (n = 12), carer support organisations (n = 13), palliative care (n = 14) and cancer care coordinators (n = 27). Estimated cost of screening was AUD$42.40 per patient.

This unique model of supportive care screening using a GA questionnaire and guided intervention is feasible, relatively inexpensive and resulted in a significant number of supportive care agency referrals. The oncology and aged-care sectors can collaborate successfully in a community setting.

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P126 Effect of enobosarm, a selective androgen receptor modulator (SARM), on physical function in middle aged and elderly cancer patients, with <5% or ≥5% weight loss
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Purpose: Cachexia has been defined as >5% weight loss; however, limited data exists on the prevention and treatment of muscle wasting prior to becoming cachectic. Cancer-induced muscle wasting begins early in the disease process, resulting in decreased physical function and other detrimental consequences. Cancer patients with muscle wasting are less able to tolerate chemotherapy, have worse treatment outcomes, lose independence, and exhibit shorter overall survival. We conducted a randomized, double-blind, placebo controlled study to assess the effect of enobosarm on muscle wasting and physical function in cancer patients. The purpose of this analysis is to examine the physical function response in subjects by age and extent of weight loss at baseline.

Methods: Subjects (n = 159) were randomized to oral enobosarm or placebo for 16 weeks. Subjects were males >45 years old (yo) and postmenopausal females with ≥2% weight loss in the past 6 months that had been diagnosed with non-small cell lung cancer, colorectal cancer, chronic lymphocytic leukemia, non-Hodgkin’s lymphoma or other.