MGA parameters and awareness of disease, family interference, reading of CF by proxy and probability of receiving less information, as follows:

	PS	Charlson's score	MMS	GDS	ADL	IADL
Awareness of disease	p = 0.036	ns	p < 0.001	p = 0.013	ns	ns
Family interference	p = 0.003	ns	p = 0.022	ns	p = 0.025	p = 0.031
Reading of CF by proxy	p < 0.001	ns	ns	p = 0.033	p = 0.033	p < 0.001
Less information	p < 0.001	ns	p = 0.041	ns	p < 0.001	p < 0.001

ns = non significant

Conclusions: Our prospective cohort shows that limited and/or attenuated information is still a relevant modality of relation with elderly cancer patients undergoing chemotherapy in Italy, often in connivance with their family. Limited awareness of disease correlates with poor PS and cognitive/affective problems, while family interference is more frequent in patients with cognitive deficit and low functional status. Comorbidity does not appear to play a relevant role in the informed consent process.

1276 POSTER

Duration of onset of metastatic bone pain relief with ibandronate: phase III and phase II trial results

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Background: Bone pain is the most common reason for patients with skeletal metastases to seek treatment from their physician. This symptom is difficult to manage and often persists despite bone radiotherapy or analgesic consumption. The onset of metastatic bone pain relief with ibandronate has been evaluated in clinical trials.
Materials and methods: In a 96-week, randomized, phase III trial, ibandronate 6mg (n = 154) or placebo (n = 158) was infused over 1–2 hours every 3–4 weeks. In two phase III studies (data pooled), patients received oral ibandronate 50mg (n = 287) or placebo (n = 277) once daily. Bone pain was assessed on a 5-point scale (0 = none to 4 = intolerable). In phase II studies of patients with bone pain due to metastatic urologic cancer (n = 55) or hormone refractory prostate cancer (HRPCA; n = 45), ibandronate 6mg was infused on 3 consecutive days (18mg loading dose), followed by a single 6 mg infusion every 4 weeks. Bone pain was assessed on a visual analog scale (VAS) from 0 = no pain to 10 = maximum pain. Analgesic use was recorded in a diary and functioning by the Karnofsky index.
Results: In a phase III trial, intravenous ibandronate 6mg reduced bone pain below baseline within 4 weeks (maximal effect by Week 12). At endpoint, the mean change from baseline was −0.28 vs +0.21 with placebo ($p < 0.001$). Oral ibandronate 50 mg also reduced bone pain below baseline within a few weeks; this was maintained for 2 years (−0.20 vs +0.10 with placebo at Week 96; $p = 0.001$). In the urologic cancer study, 73% of patients (40/55) had pain relief (≥ 3-point VAS reduction) by Day 2 following loading-dose ibandronate, reaching statistical significance on Day 3 (2.5 vs 6.8 at baseline, $p < 0.001$). Eleven patients (20%) became pain-free. Analgesic use reduced by ≥50% in 64% of patients (35/55). In the HRPCA study, 40 patients (89%) had pain relief by Day 3 ($p < 0.001$). In both phase II studies pain scores remained below baseline for >20 weeks with ibandronate maintenance dosing; performance status also improved (regained mobility and independence).
Conclusions: Standard-dose ibandronate alleviated bone pain within several weeks, and for up to 2 years. Severe symptoms were reduced within days of the intravenous loading dose, suggesting that ibandronate offers rapid relief to patients who need it the most. Trial findings are corroborated by case report data. Large-scale comparative trials of oral ibandronate and intravenous zoledronic acid for metastatic bone pain are planned.

1277 POSTER

Quality of life in patients with painful bone metastases: results from the randomized Dutch Bone Metastasis Study on single fraction versus multiple fraction radiotherapy

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Background: The prospectively randomized Dutch Bone Metastasis Study evaluated the palliative effect of 8 Gy single fraction radiotherapy versus 24 Gy in 6 fractions in patients with painful bone metastases. In previous Publication onlyns, the equal effectiveness of both radiotherapy treatment schedules for treating pain was reported. Here, we focus on three specific quality of life (QOL) domains in patients with painful bone metastases.
Material and methods: 1157 patients were randomized into the study. Median overall survival was 7 months. Patients filled out 13 weekly and then monthly questionnaires for two years or until death. Questionnaires contained 48 items from EORTC QLQ-C30, Rotterdam Symptom Check List and EURO-QOL. Item scores were summarized by three component scores: physical symptoms, psychological symptoms and functional status. Mixed modeling was used to model the course of QOL during follow up, and to test differences between the two randomization groups, and between primary tumor groups (breast cancer, lung cancer, prostate cancer versus other types of cancer). Differences were expressed as effect sizes d, which can be interpreted as small (d = 0.2), medium (d = 0.5), or large (d = 0.8).
Results: In general, patients deteriorated immediately after treatment, subsequently recovered and temporarily improved, but deteriorated sharply in the last months before death. Recovery and improvement were larger in patients with a more prolonged survival. For example, patients with 18 months survival reported less physical symptoms than patients with 6 months survival (figure 1). In addition, patients who received multiple fractions reported more physical symptoms than after a single fraction (d = 0.11, $P < 0.01$), but not more psychological symptoms (d = 0.05, $P = 0.20$) or worse functioning (d = 0.01, $P = 0.80$). Patients with breast cancer reported more psychological symptoms (d = 0.20, $P = 0.02$) and worse functioning (d = 0.19, $P = 0.04$).

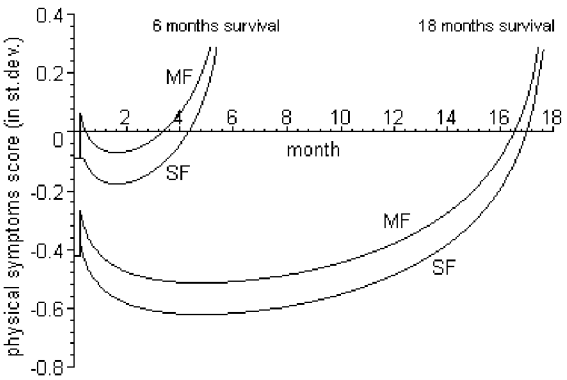

Fig. 1: Mean curve estimates of physical symptoms scores of patients who recieved either single fraction (SF) or multiple fraction (MF) radiotherapy and who survived either 6 or 18 months.

Conclusions: The course of QOL of patients receiving single fraction radiotherapy is at least as good as the QOL of patients receiving multiple fractions. Because single fraction radiotherapy provides equal palliation for treating pain it should be the standard palliative treatment for the majority of patients with painful bone metastases. Patients with breast cancer reported worse QOL than others, for that reason, further analyses of specific QOL domains related to direct treatment side effects will be presented at ECCO.

1278 POSTER

The efficacy of interleukin-6 and hypothalamus-pituitary-adrenal (HPA) axis function as predictors for the presence of depression in cancer patients

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Background: Inflammation and perturbation of the hypothalamic-pituitary-adrenal (HPA) axis function play a putative role in the ethiology of depression. Patients (pts) with metastatic cancer show elevated prevalence rates for depression. The objective of this study was to illustrate the efficacy of interleukin-6 (IL-6) and HPA axis function in predicting the presence of depression in pts with cancer.
Methods: 114 patients with metastatic cancer were assessed by the Hospital Anxiety and Depression Scale (HADS) for Depression and diagnoses was established according to the DSM-IV criteria. A level of ≥ 11 was considered significant on the HADS-D axes for Depression. Plasma concentrations of IL-6 were measured in addition to cortisol levels (8AM and 8PM). The relative diurnal variation of cortisol (cortisol VAR), expressed in percent, was calculated as measure of the circadian function of the HPA

axis. In the statistical analysis the Mann-Whitney test and the receiver operating characteristic (ROC) analysis were applied.
Results: Mean age and Karnofsky-index were not significantly different between cancer pts with depression and cancer pts without depression. There was a significant difference in median plasma concentration of IL-6 between the cancer pts with depression and without depression (18.7 vs. 2.7 pg/ml; $p < 0.001$). Plasma cortisol concentrations (8AM and 8PM) were significant higher in depression. The relative cortisol VAR (11.7 vs. 60.6% respectively; $p < 0.001$) was significantly decreased in the cancer pts with depression compared the in the cancer patients without depression, indicating a reduced diurnal amplitude in cortisol concentration demonstrating a disturbed circadian function of the HPA axis. IL-6 concentrations yielded as a predictor for the presence of depression at a cutoff value of 10.6 pg/ml a sensitivity of 79% and a specificity of 87% (AUC = 0.86; 95% CI 0.78–0.94), whereas cortisol VAR showed a sensitivity of 81% and a specificity of 88% (AUC = 0.85; 95% CI 0.74–0.97) at a cutoff value of 33.5%.
Conclusions: Depression is associated with increased plasma IL-6 concentrations in pts with cancer. These pts show a dysfunction of the HPA-axis, characterized by increased cortisol levels and a decreased diurnal variation of cortisol. The high sensitivity and specificity of these parameters for the presence of depression at the respective cutoff values make IL-6 and cortisol VAR helpful tools in the diagnosis of depression in pts with cancer.

1279 POSTER

Age does not influence acute toxicity during radiotherapy dose escalation for prostate cancer

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Background: Following the Publication onlyn of numerous studies, we have escalated our standard dose for the radical treatment of localised prostate cancer from 64 Gy to 74 Gy. With the disease being predominant in elderly men, we prospectively assessed whether the elderly have a higher incidence of acute toxicity.
Materials and methods: Random sample of 59 patients treated with radical conformal prostate radiotherapy over a 12-month period at a single institution. All patients had histologically proven prostate cancer and weare staged with a body coil MRI scan. Patients were positioned supine with knee supports using no rectal immobilisation and keeping the bladder comfortably full. Radiotherapy was planned using Helax TMS 6.1 B software and dedicated CT planning scans. All patients had 3D conformal radiotherapy with four field plans (Ant, Post, R. Lat, L. Lat beams). Patients were treated with an Elekta linear accelerator using 10 MV photons. Most (86%) were treated with a two-phase treatment plan. Patients were regularly reviewed at weekly intervals during radiotherapy and acute toxicity data (graded using CTC criteria) was collected prospectively using a standardised template. Statistical calculations were performed with chi-square or Mann Whitney U test as appropriate using SPSS for windows version 11.0.0 (SPSS Inc. Chicago, Illinois, USA).
Results: The median age of our sample was 67 years (range 53–81). The median Gleason score was 7 (range 6–10). The median PSA was 15.6 (range 1–95.4). The T stage of the tumours was T1 (34%), T2 (44%), T3 (15%), T4 (7%). The median radiotherapy dose was 72 Gy (range 64–74 Gy). The median number of fractions was 36 (range 31–38) with fraction size being 1.8–2 Gy. Neoadjuvant hormone therapy for 3 months prior to radiotherapy was given to 80% of patients. Overall, the acute GI/GU toxicity following radiotherapy dose escalation was found to be acceptable. No patients experienced grade 4 toxicity. Neither age, radiotherapy dose, use of neoadjuvant hormones, anterior field size area or pre-treatment tumour characteristics were found to significantly influence acute toxicity (table 1).

Table 1

	Age under 70 years			Age over 70 years			P value
CTC toxicity criteria	Grade 1	Grade 2	Grade 3	Grade 1	Grade 2	Grade 3	
Bladder Frequency	28%	28%	15%	25%	35%	20%	0.40
Dysuria	39%	15%	5%	20%	10%	0%	0.40
Rectal bleed	21%	0%	0%	20%	0%	0%	0.96
Diarrhoea	26%	5%	0%	15%	0%	5%	0.42

Conclusion: Elderly men with localised prostate cancer tolerate radiotherapy dose escalation without a considerable increase in acute toxicity and should not be denied dose escalation, on the basis of potential acute toxicity, if it is felt to be clinically appropriate.

1280 POSTER

Exercise during cytostatic treatment: correlates of cancer patients' self-reported anxiety and depression

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Background: Little is known about the role of exercise in improving cancer patients' mood while undergoing chemotherapy. The primary aim of the current study was to examine the effects of a six-week, supervised exercise program on self-reported psychological distress. Firstly, it was hypothesized that the exercise intervention would have beneficial outcomes on both anxiety and depression, and secondly, that this positive outcome would be associated with improvement in aerobic capacity. Material and
Methods: A heterogeneous sample of 91 patients undergoing chemotherapy was included. Eighty percent of the sample was oncology patients of whom 40% were women with breast cancer. 54% of the patients showed evidence of disease indicating residual or progressive disease, while 46% showed no evidence of residual disease and were treated with adjuvant therapy. The reported level of physical activity at baseline showed that 37% of the population had sedentary lifestyles. Patients completed a Hospital Anxiety and Depression Scale Questionnaire (HADS) (response rate 91%), Aerobic capacity (VO_2max) was indirectly estimated by use of a stepwise work capacity test on an exercise bicycle.
Results: Adherence to the programme was 78%. Anxiety ($p < 0.001$) and depression ($p = 0.042$) was significantly reduced. The mean $\pm$ SD of the change was -1.14 ± 2.91 for anxiety and -0.44 ± 2.77 for depression. VO_2max significantly increased, $t(83) = 7.10$, $p < 0.001$. On average there was an increase of 0.272 l/min. equal to 12%. Improvements in fitness were correlated with improvements in depression, $\chi^2(1) = 3.966$, $p = 0.046$, but not with improvements in anxiety, $\chi^2(1) = 0.540$, $p = 0.462$. The study furthermore indicates that distress may be associated with gender, $F(1,89) = 6.96$, $p = 0.009$, disease status, $F(1,89) = 4.56$, $p = 0.035$, and pre-intervention levels of physical activity, $F(1,89) = 4.40$, $p = 0.038$.
Conclusion: The research suggests that exercise intervention may have a beneficial impact on psychological distress for cancer patients receiving chemotherapy with low to moderate levels of baseline psychomorbidity. The study is followed-up by an ongoing randomized clinical controlled trial including 250 patients to evaluate potential causal effects of exercise intervention on psychological distress and fitness in cancer patients undergoing chemotherapy.

1281 POSTER

Effect of patient age on the prevalence and treatment of anemia as defined by the European Cancer Anaemia Survey (ECAS)

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Background: Cancer-associated anemia occurs as a result of the treatment and the malignancy. Data from ECAS (Ludwig et al, *Eur J Cancer* 2004;40:2293–2306) were analyzed to evaluate any differences in the prevalence and treatment of anemia (hemoglobin [Hb] < 12.0 g/dL) according to patient age at diagnosis, and effect of anemia on quality of life (QOL).
Material and methods: Data were used from the analysis population (patients with data at and after enrollment; n = 13,628). Data included treatment status (none, chemotherapy [CT], radiotherapy [RT], concomitant CT/RT); Hb levels; and QOL as measured by WHO performance score; all tumor types were included. Age groups were defined as (years)18–49, 50–59, 60–69, and $\geqslant 70$; approximately the same percentage of patients was in each age group at enrollment: 25%, 26%, 29%, and 20%, respectively.
Results: No differences in treatment status at enrollment were noted among the age groups. Slightly over half the patients were receiving no treatment (range among age groups: 52% to 55%), about 40% (range: 38% to 40%) were receiving CT, and some (range: 4% to 5%) were receiving RT. At 1 month post-enrollment, CT and RT were administered to more patients (62% to 70%, and 11% to 16%, respectively); patients $\geqslant 70$ received less CT and more RT compared with the other age groups. Hb level at enrollment did not differ significantly among age groups although anemia was noted in greater percentages of older patients (60–69 years: 40%; $\geqslant 70$ years: 44%) compared to younger patients (18–49 years: 38%; 50–59 years, 36%). About 30% of patients across age groups had Hb levels between 10.0 and 11.9 g/dL; slightly more patients in the older age groups had Hb levels < 10.0 g/dL (60–69 years: 12%; $\geqslant 70$ years: 13%)