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

CTC toxicity criteria	Age under 70 years			Age over 70 years			P value
	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 radio-therapy 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 ± 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 ≥ 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 ≥ 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%; ≥ 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%; ≥ 70 years: 13%)

compared to younger patients (18–49 years: 9%; 50–59 years, 9%). At 6 months post-enrollment, a greater percentage of patients $\geqslant$ 70 years of age were anemic (54%) compared to patients in the other age groups (range: 44% to 48%) and a greater percentage of these elderly patients had Hb levels < 10.0 g/dL (14%) compared to the other age groups (range: 10% to 11%). Overall, increasing age had a negative effect on WHO performance score at enrollment and during the 6-month survey; patients $\geqslant$ 70 years had consistently lower WHO scores compared to younger patients. The majority of patients (72% overall) did not receive anemia treatment after enrollment. For patients who did receive treatment, more were in the older age groups (60–69 years: 29%; $\geqslant$ 70 years: 31%) compared to younger patients (18–49 years: 25%; 50–59 years, 27%). Patients $\geqslant$ 70 years received the most epoetin (16%) compared to other age groups (11% to 13%).

Conclusions: Patients of all ages have significant anemia, although elderly patients appear to have more anemia overall with lower Hb levels and worse WHO performance scores. Effective anemia treatment should be administered to cancer patients regardless of age to insure optimal patient management.

1282 POSTER

Economic analysis of aprepitant in patients receiving antiemetic prophylaxis with moderately emetogenic chemotherapy in France – results of a decision-analytic model

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Background: Chemotherapy-induced nausea and vomiting (CINV) remains a major adverse effect of cancer chemotherapy. Aprepitant, a NK1 receptor antagonist, represents a new approach to antiemetic therapy.

Objective: To evaluate the economic implications of treatment with aprepitant relative to standard therapy for French patients undergoing moderately emetogenic chemotherapy (MEC)

Methods: A decision analytic model compared a 3 day aprepitant regimen (Day 1: aprepitant 125 mg P.O. in combination with ondansetron 8 mg P.O. twice daily and dexamethasone 12 mg P.O.; Day 2–3: aprepitant 80 mg P.O. once daily) to standard therapy (Day 1: ondansetron 8 mg P.O. twice daily and dexamethasone 20 mg P.O.; Day 2–3: ondansetron 8 mg P.O. twice daily) over a single chemotherapy cycle. The model was based on clinical results and healthcare resource utilization observed in a large clinical trial of aprepitant in MEC. Trial outcomes included complete response (no emesis, no rescue therapy), impact of CINV on daily life, and quality-adjusted life years (QALYs). QALY data were obtained from the literature. French costs were used to cost health care resources: a) hospital costs (http://www.atih.sante.fr/), b) ambulatory fees (http://www.ameli.fr/); and c) drug prices (http://www.gie-gers.fr/).

Sensitivity of results to changes in model parameters was investigated through a series of sensitivity analyses.

Results: In the aprepitant group (n = 429) 51.3% of the patients were complete responders over the entire chemotherapy cycle compared to 42.7% in the standard care group (n = 422). More patients were CINV-free over the entire chemotherapy cycle with aprepitant regimen (54.1%) compared to standard regimen (46.0%). Expected cost difference between aprepitant regimen and standard therapy was *1.07, with 98% of the aprepitant cost offset by savings in 5HT3 drug costs and healthcare resource use. Expected marginal cost-per-QALY-gained with aprepitant was *1,890. Results were robust with respect to all healthcare resource utilization costs, and most sensitive to costs of prophylactic 5HT3s and utilities for CINV health states.

Conclusion: Patients receiving aprepitant-based treatment for MEC had better CINV-related outcomes compared to patients receiving standard regimen with nearly all of the drug cost of aprepitant being offset. An aprepitant-based treatment for prevention of CINV in MEC patients appears to be cost-effective in France.

1283 POSTER

Darbepoetin alfa administered once every 3 weeks (Q3W) is effective for treating anaemia in patients receiving multicycle chemotherapy: results of a randomised, double-blind, active-controlled trial

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Background: Darbepoetin alfa (Aranesp®; DA) is licensed in Europe for the treatment of chemotherapy-induced anaemia using either once weekly (QW) or Q3W administration. The Q3W schedule is convenient because it can be synchronized with many chemotherapy regimens, resulting in fewer visits and reduced burden to patients (pts). This study evaluated the comparability (non-inferiority) of a fixed starting dose of 500 mcg Q3W with 2.25mcg/kg QW DA, with respect to efficacy and safety.

Methods: This was a randomised, double-blind, double-dummy, active-controlled phase 3 study in 110 centres across Europe. Eligible subjects were $\geqslant$ 18 years of age, anaemic (haemoglobin [Hb] < 11 g/dL), and diagnosed with a non-myeloid malignancy with $\geqslant$ 12 weeks of planned chemotherapy. Pts were randomised 1:1 to Q3W or QW DA for 15 weeks. The primary endpoint was incidence of red blood cell transfusions from week 5 to end of treatment phase. Non-inferiority was determined if the 95% confidence interval (CI) of the difference in transfusions between groups did not exceed a pre-specified margin based on previous placebo-controlled studies of DA 2.25 mcg/kg QW. The primary analysis included pts who received $\geqslant$ 1 dose and who were enrolled in the study until at least day 29. Secondary endpoints included change in Hb and FACT-F, and achievement of Hb $\geqslant$ 11 g/dL.

Results: 705 pts were randomised; 672 were analysed for the primary endpoint. Demographic characteristics were similar between the 2 treatment groups. Transfusion incidence (95% CI) was 23% (19 to 28) and 30% (25 to 35) for the Q3W and QW groups, respectively (difference: −6.8 percentage points [−13.6 to 0.1]) We observed a similar difference in transfusion requirements between treatment groups after adjusting for stratification factors, and for pts with haematological and solid tumours. The proportion of pts achieving Hb $\geqslant$ 11 g/dL was 84% (Q3W) and 77% (QW); pts achieving the dose-withholding limit of Hb $\geqslant$ 13 g/dL was 24% (Q3W) and 22% (QW). The safety profile was similar for the 2 treatment groups, with no association between cardiovascular/thromboembolic adverse events and rapid rise in Hb levels or Hb $\geqslant$ 13 g/dL. Fifty-seven percent (Q3W) and 58% (QW) of pts had $\geqslant$ 3-point increase in FACT-F. In the Q3W arm, the median number of doses was five compared with 14 doses in the QW arm.

Conclusions: The Q3W regimen was comparable to the QW regimen since the upper limit of the CI of the transfusion incidence fell substantially below the pre-determined non-inferiority margin. These results demonstrate effective anaemia management with less frequent dosing of DA.

1284 POSTER

ECAS, MEWACAS and ACAS: Contrasts and comparisons of three regional, multinational, prospective anemia surveys in cancer patients

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Background: European Cancer Anaemia Survey (ECAS) was the first survey to evaluate prospectively and objectively the prevalence, incidence, and management of anemia (Ludwig et al, EJC 2004) and define predictive risk factors for anemia (Van Belle et al, Ann in Oncol 2004 abstract) in a large population of cancer patients (pts). Pts (n = 15,367) with solid (78.9%) and hematological malignancies (21.1%) from 24 countries in 824 centers were followed for up to 6 months. Data demonstrate a high prevalence of anemia (67%) in cancer pts, particularly those undergoing chemotherapy (CT) [75%] and with no cancer therapy (40%), with an adverse effect on WHO performance status.

Methods: To facilitate comparable data on anemia from cancer pts in the Middle East/Western Asia (MEWA) region, the MEWA Cancer Anaemia Survey (MEWACAS) was instituted, a prospective, epidemiologic, observational survey conducted in 11 countries, including Cyprus, Egypt, Iran, Israel, Jordan, Kuwait, Lebanon, Libya, Malta, Saudi Arabia, and the United Arab Emirates. Additionally, a similar data collection record form was used in Australia in 24 cancer centres (Seshadri et al, MJA 2005) for the Australian Cancer Anaemia Survey (ACAS).

Results: Demographics of the three surveys differed slightly (see table below). There were 921 patients enrolled in MEWACAS and 694 pts were