Results: The 26% of Littlewood HM pts who met NOW criteria experienced substantially better outcomes than those who did not. Table 1 compares the results of NOW-eligible and NOW-ineligible Littlewood HM pts.

Table 1.

	NOW-ineligible Littlewood HM pts n=124	NOW-eligible Littlewood HM pts n=43	Outcomes difference
Change in Hb during study	2.0 g/dL	2.6 g/dL	30%
TF required	44 (35.5%)	6 (14.0%)	254%

NOW pts receiving epoetin beta 30,000 IU QW experienced a 2.0-g/dL change in Hb (Cazzola 2002), 0.6 g/dL less than the NOW-eligible patients from the Littlewoood HM cohort.

Conclusions: The application of NOW exclusion criteria selects for significantly improved patient outcomes. These results suggest that HM pts who do not meet NOW criteria may have a lesser response to rHuEPO dosed at 30,000 IU QW. This regimen should be used with caution in a carefully selected subset of patients. Further studies should establish an optimal weekly rHuEPO dosing regimen for anemia correction in a broad range of HMs.

943 POSTER

Early administration of hemoglobin-adapted doses of erythropoietin with intravenous iron for the prevention of chemotherapy-induced anemia

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Background: Treatment of chemotherapy (CT)-induced anemia requires high doses of erythropoietin (EPO) and time to response usually takes 4 weeks (w). A functional iron deficiency due to underlying cancer prevents a quick and full response to EPO. We tested the feasibility of an early administration of EPO (Eprex ®) given with intravenous (iv) iron (Venofer ®) for the prevention of anemia.

Patients and methods: Chemonaïve, non-anemic (hemoglobin (Hb) > 11 g/dL) patients (pts), due to receive at least 3 cycles of a platinum-based CT were included. Subcutaneous EPO 10'000 U three times a week (3x/w) and iv iron 100 mg once a week were initiated as soon as Hb declined under 13 g/dL. EPO dose was adjusted according to Hb every 4 w. If Hb was stable (11-13 g/dL), the EPO dose was reduced to 4000 U 3x/w, and 4 w later to 2000 U 3x/w. If Hb was >13 g/dL, EPO was withheld and for values <11 g/dL, EPO was increased to 20'000 U 3x/w. EPO and iv iron were stopped at the end of chemotherapy or in the case of EPO resistance (Hb<11 g/dL after 4 w of EPO at 20000 U 3x/w).

Results: 37 pts have been included: male/female (26/11); PS ≤1/2 (34/3); median age 58 years (36-69); lung/other cancer (28/9); cisplatin/carboplatine-CT (33/4). Of 37 pts, 2 pts never received EPO (1 pt had a CT related hemolysis at day 15; 1 pt was non-compliant) and 2 pts had EPO interruption for safety reasons (myocardial infarction at day 16 with Hb=14.6; transient cerebral ischemia at day 7 with Hb=12) and were excluded from the efficacy analysis. For the 33 evaluable patients, the median number of CT cycles was 4 (1-6). The median duration of CT treatment was 13 w (5-20) and the median duration on EPO treatment was 8 w (0-20). EPO was withheld in 40% of the treatment time, because of Hb>13 g/dL. Decrease from 10000 dose level to 4000 and 2000 was realized in 33% and 21% of the pts, respectively. Increase to 20000 was necessary in 9 pts (27%) and EPO resistance was seen in 7 pts (23%). The mean EPO dose required per pt was 5678 U 3x/w. Mean Hb level was 13.4 ±1.5 g/dL at the start of CT and 10.8 ±1.8 g/dL at the end of CT. At the end of CT, Hb>11 g/dL was achieved in 18/33 pts (55%). NCI-CTC grade 2 anemia (Hb<10 g/dL) was prevented in 24/33 pts (72%) and only 3 pts required blood transfusions. No side-effects occurred with iv iron administration.

Conclusions: This monthly, hemoglobin-adapted, dose-reducing EPO regimen with iv iron allowed a 43% reduction of the standard starting dose (10'000 U 3x/w in pts Hb<10.5). Prevention of NCI-CTC grade 2 anemia (Hb<10 g/dL) was achieved in 73% of the patients. Early use of EPO with iv iron in the prevention of chemotherapy-induced anemia is a promising supportive treatment that should be compared to the standard practice of beginning EPO later in cancer patients once anemia has already occurred.

First and second authors contributed equally to the work.

Eprex ® was supplied by Janssen-Cilag CH and Venofer ® by Vifor CH.

944 POSTER

Does selective gut decontamination in oncology patients reduce the number of bacteraemia's?

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Introduction: Infectious complications remain a source of morbidity and mortality in oncology patients. Selective decontamination of the digestive tract (SDD) was introduced in the 70's by administration of oral partly absorbable and partly non-absorbable antibiotics, often in combination with anti-fungal prophylaxis to reduce infections. Despite the amount of studies involving SDD, there is still no consensus whether SDD should be given and what antibiotic to use. In this systematic review we will assess the efficacy of TMS, fluoroquinolones and fluoroquinolones plus an antibiotic covering gram positive infections.

Objectives: To identify all randomized controlled trials evaluating the reduction of bacterial infections by SDD in oncology patients (both adults and children) who are receiving chemotherapy with expected neutropenia.The main outcome is documented bacteraemia during episodes of using SDD.

Search strategy: We performed a computer-assisted search using Medline from 1966 to October 2002, Embase 1966-2002 and the Cochrane Database.The computer search was supplemented by checking the references of these articles for additional papers.

Data collection & analysis: The studies identified were assessed and the data extracted independently by the two reviewers and a quality assessment was carried out using a quality list (Tulder).

Results: 59 articles were included of which only 18 articles fullfilled the strict criteria of metholodogical quality. Analyzing the results comparing studies using SDD to placebo favoured treatment OR 0.46 (CI 0.32-0.64) to prevent bacteraemia in the neutropenic patient. Analysis of subgroups showed comparable results for TMP/SMZ vrs placebo OR 0.39(CI 0.18-0.86) and for quinolones OR 0.31 (CI 0.17-0.58). Gram-negative bacteraemia's are also prevented in the total group OR 0.35(CI 0.21-0.58), whereas SDD does not prevent Gram-positive bacteraemia's OR 0.68 (CI 0.43-1.05).

Conclusions: By performing the extended literature search, and performing a quality-assessment independently by 2 reviewers it can be concluded that in patients with neutropenic episodes it is possible to reduce the chance of bacteraemia's, mainly gram-negative bacteraemia's by providing selective decontamination of the digestive tract.

945 POSTER

Analysis of pooled data from two Phase III studies of the NK-1 antagonist aprepitant to assess relationships between the incidence and control of cisplatin-induced acute vomiting and delayed vomiting.

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Vomiting that occurs 24-120 hours after administration of chemotherapy (delayed vomiting) (DV) can be correlated with acute vomiting (AV), which occurs during the first 24 hours after chemotherapy. If the correlation represents an unfavorable "carryover" effect, then prevention of AV should be sufficient to prevent DV. We explored the relationship of AV and DV using pooled data from 2 identically designed randomized double-blind Phase III studies of aprepitant (Ap), in which 1034 patients (pts) receiving high-dose cisplatin were given either a standard antiemetic regimen (SAR) consisting of ondansetron (O) 32 mg iv and dexamethasone (D) 20 mg po on day 1, and D 8 mg po bid on days 2-4; or an Ap-based antiemetic regimen (ApAR) consisting of Ap 125 mg po, O 32 mg iv, and D 12 mg po on Day 1, Ap 80 mg po and D 8 mg po on Days 2-3, and D 8 mg po on Day 4. Pts were categorized by the presence or absence of AV, and the incidence of DV was then evaluated between categories. Within each category of AV response, a between-treatment comparison of DV was also made (Table).

AV	DV	ApAR (pts)	SAR (pts)
Yes	Yes	47	116
Yes	No	22	20
No	Yes	77	127
No	No	374	260

Of the 838 pts with no AV, 634 (76%) had no DV. However, of the 205 pts with AV, only 42 (20%) had no DV. Among the 838 pts with no AV, 374/451 pts (83%) receiving ApAR had no DV while 260/387 pts (67%) receiving SAR had no DV. This advantage was also observed among the 205 pts with

AV, of whom 22/69 pts (32%) receiving ApAR had no DV while 20/136 pts (15%) receiving SAR had no DV. Although pts with no AV were more likely to have no DV, 204/838 pts (24%) with no AV still had DV. However, the similar magnitude of improvement in the prevention of DV with ApAR in pts with AV (17%) and with no AV (16%) showed that the effect of Ap on DV is a pharmacologic effect rather than simply a "carryover" effect of prevention of AV.

946 POSTER

Compulsory constipation? - an evaluation of the prevalence and management of constipation in palliative care

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Background: Constipation is a side effect of many drugs commonly used in palliative care. About 50% of patients admitted to British hospices cite constipation as a major concern. There has been little evaluation of the effectiveness of constipation management or assessment of the effect of constipation on the quality of life of patients with palliative care needs. A multi-centre study was conducted to evaluate; 1) how effectively constipation is managed in different palliative care settings; and 2) any differences in perceptions of the effect constipation has on quality of life between patients and their carers.

Methods: Patients (in-patient and day therapy) were recruited from the Marie Curie Cancer Care specialist palliative care services across the UK. Self administered questionnaires incorporating the Patient Assessment of Constipation Symptoms, the Palliative Care Outcome Scale and study-specific questions were completed by patients, their named nurse and where possible their main family carer. Informed consent was obtained. Questionnaires were completed on day 1 and 7 - 10 days later.

Results: 413 patients completed both questionnaires (207 in-patients and 206 day patients).

Conclusions: Results from the questionnaire data will be discussed. Differences in the management of constipation across the care settings will be highlighted together with variations in patients' perception of constipation and actual constipation symptoms. Laxative efficacy varied between individuals supporting the notion that laxative type and dose should be titrated to patient response. Variations in perception of the impact of constipation on quality of life between patients and their carers will be discussed.

947 POSTER

Chemotherapy-associated anemia in breast cancer patients: Prevalence and incidence from the European Cancer Anemia Survey (ECAS)

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New treatment (tx) regimens and chemotherapy (CT) agents have increased chances for survival for breast cancer (BC) patients (pts). Anemia remains a significant adverse effect of BC and its tx, and is reported in substantial numbers of pts treated with conventional and new agents (Groopman 1999). The large, prospective, multinational ECAS followed pts for up to 6 months to evaluate prevalence and incidence of anemia (hemoglobin [Hb] /=12 g/dL, respectively. Only 26% of BC pts who had anemia during ECAS received anemia tx. Mean Hb level was 9.0 g/dL for first transfusion and 10.4 g/dL for first administration of epoetin. These results show that the prevalence and incidence of anemia in pts with BC is high regardless of CT regimen. Anemia is a serious consequence of tx with newer agents and regimens, as well as standard, non-platinum regimens. Despite the significant negative impact of anemia on PS, most anemic BC pts did not receive anemia tx.

948 POSTER

The "comprehensive geriatric assessment" evaluation: a selection of informative questionnaires for essential parameters. Preliminary experience by a single institution

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Comprehensive geriatric assessment (CGA) is a structured approach aiming at measuring the most important parameters to identify needs and to plan care in elderly patients. They may be identified as: functional, cognitive, presence of comorbidity and nutritional. The selected instruments were: the activity of daily living (ADL) and the instrumental activities of daily living (IADL) scales in addition to PS for function, the Mini-Mental Status Examination and the Beck's Depression Inventory (cognitive); the Charlson's scale (comorbidity) and the Mininutritional Assessment (MNA) for nutrition. The aim of our study was to develop a best-practice model both exhaustive and feasible for geriatric assessment of elderly cancer patients (i.e. aged 65 years or older). 58 elderly patients (M/F: 31/27, mean age 72 years, range 65-86) with cancer at different sites were assessed. 10% of patients had stage II, 22% stage III and 68% stage IV disease. 13.8% of patients had PS 0, 62% PS 1, 13.8% PS 2, 5.2% PS 3 and 5.2% PS 4. Overall, 46.6% of patients had no limitations for ADL, 6.8% were completely dependent. Approximately 30% of patients had no limitations for IADL. 53.4% showed symptoms of depression (15.4% of them had an heavy depression). 39.7% of patients showed a mild to serious cognitive defects: no correlation was observed with increasing age and education. 43.1% of patients showed comorbidities and 17.3% were malnourished. Patients showed an optimal compliance for the instruments used. The study is ongoing to assess the prognostic role of CGA on the disease outcome.

949 POSTER

Fecal human DNA as a marker of intestinal toxicity in patients undergoing abdominal radiotherapy

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Background: Radiotherapy can damage intestinal tissues and impair gut function. Specifically, radiation impairs crypt cell proliferation and induces epithelial denudation and atrophy. Acute toxicity is manifested by symptoms of diarrhea, proctitis and colitis. There is no reliable biological marker to evidence and quantify intestinal toxicity. The aim of the study was to evaluate the relations between acute intestinal toxicity and epithelial exfoliation in patients submitted to therapeutic pelvic radiation.

Material and methods: Twenty-four patients ongoing radiotherapy for various tumour sources were studied: 54% rectum, 25% endometrium, 13% cervix uteri and 8% prostate. Four stool samples were collected on each patient (before starting the treatment, between the second and third week of radiotherapy, at the end of treatment and two weeks later). Exfoliation of the epithelium was determined in these samples by quantitative PCR amplification of a fragment of the human beta globine gene from purified DNA. This gene is not encountered in bacteria present in the gut, and therefore specific for host DNA. Results were expressed as copies of DNA per milligram dry weight of stool. In parallel, severity of diarrhea associated with radiotherapy was scored according to the CTC (Common Toxicity Criteria) into four levels: degrees 0 to 3 of diarrhea.

Results: Fecal DNA levels expressed as median (range) in the four groups classified according to severity of diarrhea were: Degree-0: $1.8x10^3$ ($7.0x10^1$ $4.6x10^4$); Degree-1: $4.2x10^3$ ($3.9x10^2$ $1.1x10^6$); Degree-2: $2.2x10^4$ ($1.2x10^3$ $3.4x10^6$); Degree-3, $1.1x10^4$ ($8.0x10^2$ $6.2x10^6$). Analysis of variance (Kruskal-Wallis) showed statistical differences among groups (p=0.006). Spearman's rank correlation between fecal DNA and severity of diarrhea was significant (r=0.33, p=0.002).

Conclusions: Fecal DNA may be a good quantitative marker of intestinal radiotoxicity.

950 POSTER

Darbepoetin alfa significantly improved fatigue in patients with lymphoproliferative malignancies undergoing chemotherapy: results of a phase 3 multicenter, randomized, double-blind, placebo-controlled study

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Background: Anaemia-related fatigue is associated with reduced quality of life in patients undergoing cancer chemotherapy. Elevation of haemoglobin by treatment with erythropoietic agents, darbepoetin alfa and recombinant human erythropoietin, has been shown to reduce fatigue and improve other patient-reported outcomes in patients with solid tumors (Kallich et al, 2002; Berndt et al, 2002). This phase 3 study in patients with lymphoproliferative