1126 POSTER

Epoetin beta once-weekly (QW) treatment in anaemic patients with solid tumour receiving chemotherapy

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Background: Patients with cancer receiving chemotherapy often have chemotherapy-induced anemia and reduced quality of life. Epoetin beta (E) is an effective treatment of chemotherapy-induced anemia in patients with solid tumors (ST). Once-weekly administration of epoetin beta is convenient and may improve patient compliance by providing a patient-focused, simple treatment regimen when compared with the traditional three times weekly regimen. This study aimed to evaluate efficacy and safety of E 30 000 IU QW in patients with ST across a wide range of cancer types.
Methods: This was a multicenter, open-label, prospective, single-arm study carried out in 87 French centers between December 2003 and August 2005. Eligibility criteria were: informed consent, age $\geqslant$18 yrs, WHO performance status 0–2, malignant ST or non-myeloid hematological malignancy receiving or scheduled to receive further chemotherapy and anemia: hemoglobin (Hb) 11 g/dl at baseline respectively). Delay of Hb response, and transfusion requirement were also assessed. Here we focus specifically on the subgroup of patients with ST.
Results: In total, 365 patients with ST were included. The most frequent cancer types were: lung (102 pts) and breast (86 pts). Median Hb level at baseline was 10.4 g/dl [7.9−12.3]. At endpoint, median Hb level increased to 12.5 g/dl [8.4−15.0]. After 4 weeks of E treatment, median Hb level increased 1.1 g/dl. Hb response rate (RR) was 60.5% in all patients with ST; 54% in lung (CI95: 44−64), and 76% in breast (CI95: 67−85). RR was: 58.5% (CI95: 52−65) in patients =70 years old; 50% (CI95: 38−55) in patients treated with platinum based regimen and 72% (CI95: 62−76) in patients treated without platinum; 58% (CI95: 51−65) in patients in first and 64% (CI95: 56−71) $\geqslant$ second line of treatment; 58% (CI95: 46−70), 61% (CI95: 55−68), 61% (CI95: 50−72) respectively in patients with baseline Hb level =11 g/dl. 17% of patients with ST were transfused during the study. Thromboembolic events occurred in 7.4% of patients, a rate consistent with information provided in the current label for E.
Conclusion: Epoetin beta 30 000 IU once weekly is effective and well tolerated in anemic patients with solid tumor treated with different types of chemotherapy. Once weekly treatment offers a convenient administration and may improve patient compliance.

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Effects of dietary counselling on gastrointestinal complications and quality of life: a randomised controlled trial in prostate cancer patients undergoing radiotherapy

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Background: The incidence of prostate cancer is increasing rapidly in Sweden. Curative modalities in the management of prostate cancer include external beam irradiation with brachytherapy or proton radiation therapy. Radiotherapy can cause treatment-related complications from the intestinal tracts. Such complications have a negative effect on quality of life and therefore become a major limiting factor to the total radiation dose prescribed.
Purpose: To investigate the effect of a diet reduced in insoluble dietary fibres and lactose on gastrointestinal complications and quality of life with prostate cancer patients undergoing radiotherapy. Inclusion from January 2006 until January 2008, resulting in fully 200 patients. Data collection for a total of 26 months for each patient.
Patients and Methods: Up to April 2007, 113 prostate cancer patients referred to radiotherapy were randomly assigned: intervention group (IG; n = 56) dietary counselling (reduced intake of insoluble dietary fibres and lactose); and control group (CG; n = 57) no dietary counselling (ad libitum intake).
Gastrointestinal symptoms (study-specific questionnaire), QoL (European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire version 3.0; EORTC QLQ-C30 and the prostate cancer module EORTC QLQ-PR25) and nutritional intake (study-specific FFQ) were evaluated at baseline, at 4 and 8 weeks, and 2 months after radiotherapy. Nutritional status (Scored Patient-Generated Subjective Global Assessment; PG-SGA) and a 24h-recall were evaluated at baseline. At 4 and 8 weeks, IG conducted a 4-day food record.
Results: Preliminary analyses show that the intervention may decrease gastrointestinal toxicities in men with prostate cancer referred to radiotherapy. Preliminary analyses of food intake showed that IG followed dietary advices and significantly reduced intake of food groups rich in dietary fibres. Results will be presented.

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Risk assessment model for chemotherapy-induced anemia in patients with solid tumours: DELFOS Study

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Background: Chemotherapy-Induced Anemia (CIA), a major side effect of systemic cancer chemotherapy (CT), has been consistently associated with poor outcome of cancer patients (pts). Anemia management might be improved if clinicians were able to identify pts at risk for developing anemia during the CT. The aim of the present work is to determine a predictive model for CIA during the first three CT cycles in pts with solid tumours (ST).
Materials and Methods: Data were obtained from the DELFOS Study, a multicentre, non-interventional, prospective cohort study in Spain. This study has completed enrollment and data were available for this planned analysis. To obtain the predictive logistic regression model (LRM), the hierarchical principle was followed as a way to enable results replication. The model was implemented for CIA defined as anemia grade $\geqslant$2 (hemoglobin [Hb] < 10 g/dL). Pts who were anemic at baseline according to this criterion were excluded from the studied sample to avoid bias. A receiver operating characteristics (ROC) curve was used to determine the model's sensitivity and specificity.
Results: A total of 1,140 pts (57.3% women; 60.7% $\geqslant$55 years of age; all had ECOG score $\leqslant$2) with ST (breast 38.1%; lung 17.5%; colorectal 14.3%; other 30.1%) and baseline Hb > 10 g/dL were included from 88 Spanish oncology centers. The LRM obtained predicting CIA ($p_{Chi-sq} < 0.0005$) revealed the following predictive factors: gender, age, baseline Hb, cancer type, treatment intention, and platinum-based chemotherapy (PBC). Risk factors and effect sizes were: male gender (p = 0.011, OR = 2.09, 95% CI: 1.19, 3.68), age $\geqslant$55 years (p = 0.031, OR = 1.62, 95% CI: 1.05, 2.52), receiving non-adjuvant treatment (p < 0.007, OR = 1.91, 95% CI: 1.19, 3.05) and PBC as treatment (p = 0.003, OR = 2.45, 95% CI:1.37, 4.41). Protective factors were: high baseline Hb (p < 0.0005, OR = 0.51, 95% CI: 0.43, 0.59) and colorectal cancer (CRC) (p < 0.010, OR = 0.26, 95% CI: 0.1, 0.73), reference: breast cancer). Inherent sensitivity and specificity of the model were, 73.5% and 78.1%, respectively.
Conclusions: A risk predictive model for CIA for the first three CT cycles in pts with ST in Spain was generated using clinical practice data. Six predictive factors were identified: male gender, age $\geqslant$55 years, receipt of non-adjuvant treatment, and PBC were found to be positive predictive factors, while high baseline Hb and CRC were identified as negative predictive factors.

1129 POSTER

Communicating cancer pain

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Background: The European Pain in Cancer (EPIC) survey investigated the prevalence and impact of pain in cancer patients across Europe. Results identified a lack of communication about cancer pain between patients and the healthcare professionals (HCPs) managing their pain. The Cancer Tales workbook was developed as a communication tool to support HCPs in developing more effective communication with their patients to improve both the identification and management of cancer pain.
Materials and Methods: A pilot was conducted in the UK Nov 06 – Mar 07. Following this, between 100 and 400 cancer patients (except skin cancer) suffering all stages of the disease were recruited in each of 12 European countries. Patients participated in an initial screening process to ensure they met the criteria for the study. Patients were required to:
- Have suffered pain due to cancer in the last month.
- Experience a particular level of pain ($\geqslant$5).
- Be over 18 years old.

Following screening, 50 patients per country participated in a telephone interview. The survey was produced in association with a steering

panel comprising of the European Association of Palliative Care (EAPC), European Oncology Nursing Society (EONS), the Lance Armstrong Foundation (LAF) and OPENMinds (OM).
Results: Completion of the full pan-European data set is expected in June 2007. In the UK pilot study, 400 patients were screened and 50 in-depth questionnaires completed. Results revealed:
- Pain has a major impact on quality of life.
- The burden of pain is not appreciated by HCPs.
- Pain is not adequately controlled.
- Improved communication is urgently needed between patients and their HCPs.

Conclusions: The pilot study revealed that action is needed to improve communication between HCPs and cancer patients about issues surrounding the disease. As a result, the Cancer Tales workbook has been produced. It uses themes from the play Cancer Tales, which was developed from a collection of cancer patients' personal stories, to highlight key areas for improvement in communication about cancer, and provides guidance and practical exercises. The workbook was reviewed by a European editorial board of palliative care, pain management, oncology, nursing and communications specialists.
The EPIC survey and Cancer Tales workbook are sponsored by Mundipharma International Limited, Cambridge, UK, under the auspices of the EONS and the EAPC.

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Association of borna disease virus infection with depression in cancer patients

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Background: Borna disease virus (BDV) is a RNA virus which can persistently infect neurons of the limbic system. Several seroepidemiologic data suggest an association of BDV with neuropsychiatric disorders, however inconsistent detectability has weakened a possible linkage. The objective of this cross-sectional study was to investigate, if an association exists between BDV infection and Major Depression (MD) in patients with advanced cancer receiving chemotherapy.
Methods: 55 inpatients (Pts) with metastatic cancer (Stage IV) were assessed by the Hospital Anxiety and Depression Scale (HADS) for depressive symptoms and diagnoses of major depression (MD) was established according to the DSM-IV criteria. IL-6, BDV-specific circulating immune complexes (CIC), antibodies and plasma antigens were determined by enzyme immunoassays (EIAs). In the statistical analysis the Mann-Whitney test and Spearman-Rho correlations were applied.
Results: 55 pts (age: 59.9 years; SD 10.2) had a mean Karnofsky index (KI) of 66.5% (SD 12.1). 26 pts had MD. Pts with MD showed a significant increase in BDV-specific antigens ($p = 0.050$) and antibodies ($p = 0.045$) and IL-6 ($p < 0.001$), compared to patients without MD. CIC were not increased in MD ($p = 0.53$). Depressive symptoms were more closely correlated with level of BDV antibodies ($r = -0.296$; $p = 0.028$) and IL-6 ($r = 5.6$; $p < 0.001$) than symptoms of anxiety. Symptoms of anxiety showed a significant correlation to increased age($r = -0.28$; $p = 0.042$), whereas depressive symptoms correlated more closely with a decreased KI ($r = -0.35$; $p = 0.011$). No correlations were found for level of symptoms vs. BDV-antigen or CIC.
Conclusions: In pts with metastatic cancer, MD is associated with increased levels of BDV-specific antigen and antibody. Symptoms of depression and anxiety are only correlated with increased levels BDV-antibody. Symptoms of anxiety seem to be related to age, whereas symptoms of depression are related to decreased KI.

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Osteonecrosis of the jaw (ONJ) in patients treated with Bisphosphonates (BP): the experience of the "Rete Oncologica di Piemonte e Valle D'Aosta" (North-Western Italy)

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Background: BP are very useful drugs for treatment of myeloma, metastatic bone cancers, osteoporosis, Paget's bone disease. Reports of cases of ONJ in patients (pts) treated with BPs, mainly with Pamidronate (P) and Zoledronic Acid (Z), are increasing since 2003.
Materials and Methods: Our regional ONJ Study Group (including oncologists, haematologists, maxillofacial surgeons, odontostomatologists) diffused information and guidelines for diagnosis and prevention of ONJ, even by meetings and newsletters. A case data collection form was mailed to regional specialist care centers.
Results: we identified (on March 2007) 142 cases of ONJ, after cross-checking reports from centres of maxillofacial surgery / ORL / odontostomatology (17), medical oncology (25) and haematology/internal medicine (14). Pts were affected by breast cancer (60), myeloma (45), prostatic cancer (19), other types of cancer (13), osteoporosis or Paget's disease (5). Pts characteristics: Sex: 53/89 M/F; median age 71 yrs (range 44−84). BP treatment (among 103 cases, with available data): Z in72, P in27 (19 "switched" to Z), alendronate/risedronate in 4. Clinical findings (exposed bone or infections, pain, mobile teeth, soft-tissue swelling, nonhealing fistulas) and dental comorbidities or precipitating events (as teeth extraction, periodontal surgery, dental implants, or traumatic use of dentures) were those described in recent ONJ literature. Conclusions: Our 142 cases, observed in a population of 4.3 million, are more than expected on the basis of some published estimations of incidence, for example those based on data concerning Australia (158 cases in a population of 20.3 million: 114 cancer pts, 44 with osteoporosis/Paget's disease) or even only South Australia (25 cases, out of 1.5 million) (Mavrokokki T et al, J.Oral Maxillofac. Surg. 2007). Our oncology network recommended screening of all pts under treatment with BPs, with panoramic X-rays and referral centre visit (w/o CT or MR scan in selected cases) and careful evaluation of pts candidate to be treated with BPs, with pretherapy dental care if necessary. A case-control study has been planned to search possible risk factors of ONJ (treatment- and clinical history-related). Prospective evaluation of incidence in future, after pretherapy dental care policy and avoiding (as possible) surgical dental procedures during BP treatment, is warranted. Trials about timing, duration, schedules of BP treatment are needed. The goal is optimize cost-effectiveness of BPs, preventing and minimizing a possible debilitating long-term side effect of a class of drugs otherwise very useful for cancer patients.

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A large multicenter prospective randomised trial on the treatment of death rattle in terminal care

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Introduction: death rattle is a frequent symptom (25−50%) in the terminal stage of life, but there is neither standardized treatment nor prospective investigation performed on the efficacy of anticholinergic drugs.
Methods: We designed a large multicenter prospective randomised trial in 6 Flemish Palliative Care Units. Informed consent was required from the patient or the legal trustee. At the occurrence of death rattle, patients were randomized between one of three frequently used anticholinergic drugs: (1) atropine 0.5 mg bolus s.c., followed by 3 mg/24 h. (2) Butylhyoscine bromide 20 mg bolus s.c., followed by 60 mg/24 h. (3) Scopolamine 0.25 mg bolus s.c., followed by 1.5 mg/24h. The intensity of death rattle, and side effects, were scored at 30 min, 1 h (primary endpoint), 4 h, 12 h, 24 h and further q24h. The rattle intensity score was: 0 = not audible; 1 = only audible near the patient; 2 = clearly audible at the end of the patients bed in a quiet room; 3 = clearly audible at a distance of 7 meters in a quiet room.

Intensity difference in rattle 1 h after start of therapy

Difference[a]	Number of patients			
	Atropine	Butylhyoscine bromide	Scopolamine	Total
−3	3	1	1	5
−2	13	9	7	29
−1	27	25	30	82
0.58	60	62	180	
1.6	8	5	19	
Total	107	103	105	315

[a]−3 indicates change from rattle grade 3 to grade 0, −2 from grade 3 to 1 or from grade 2 tot 0, etc.

Results: 315 patients recruited between 11–2001 and 11–2006 were eligible for analysis. The table contains the effectiveness data 1 hour after the start of the anticholinergic treatment and shows no statistical difference