1136 POSTER

Lamivudine prophylaxis for prevention of steroid containing chemotherapy-induced hepatitis B virus reactivation in chronic HBs Ag carriers with lymphoid malignancies

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Background: Chemotherapy-induced hepatitis B virus (HBV) reactivation is a serious problem in chronic HBV carriers with hematologic malignancies, especially steroid containing regimens frequently develop significant liver injury. We have performed a case-control study to test the efficacy and tolerability of lamivudine as a prophylaxis of HBV reactivation in 30 consecutive patients treated for lymphoid malignancies with steroid containing chemotherapy.
Methods: HBsAg-positive patients with lymphoid malignancy were identified from the database of the Chonbuk National University Hospital from 1995 to 2005, and their medical records were reviewed. We found that 30 patients were received chemotherapy containing high dose steroid among 43 lymphoid malignancy patients with HBsAg-postivie during same period. We divided them into 2 groups of HBs Ag patients with lymphoid malignancy as follows: Group A (n = 15) who received chemotherapy with lamivudine 100 mg daily; Group B (n = 15) without any prophylactic antiviral therapy.
Results: There were no significant differences between Group A and B in several clinical variables. HBV reactivation and elevation of ALT levels occurred in five patients (33.3%) in Group A, whereas nine (60%) of Group B. Even though there was no acute hepatic failure or death, most of patients with HBV reactivation could not receive scheduled chemotherapy and the diseases were progressed. The tolerability of lamivudine was excellent, but prolonged use may foster the emergence of mutant lamivudine-resistant HBV strain, so caution is required during the treatment and adefovir could be an alternative choice.
Conclusions: The prophylactic use of lamivudine is safe and strongly recommended for the patients with lymphoid malignancies who are candidate for steroid containing chemotherapy.

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Impact of prolonged and increased anthracyclin treatment (4AC versus 5FEC) in patients treated for operable breast cancer, on quality of life and physical rehabilitation

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Background: In 2005 the Dutch national guidelines for treatment of breast cancer were updated. Patients with operable breast cancer, who formerly received 4 cycli adjuvant chemotherapy with doxorubicine/cyclofosfamide (AC), were from that time treated with 5 cycli 5-fluorouracil /epirubicine/cyclofosfamide (FEC), based on data suggesting survival benefit. However no data exist to what extent prolonged and increased dose anthracyclines effect quality of life and rehabilitation post chemotherapy.
Aims of the study: The primary objective of this study is to evaluate the effect on quality of life, muscular strength and cardiopulmonary function after 4 AC versus 5 FEC polychemotherapy (i.e. increased and prolonged anthracycline dose). A secondary objective is to evaluate the effectiveness of an 18 week training program in breast cancer survivors.
Patients and Methods: Between March 2002 and February 2006, 75 female subjects with breast cancer participated in a prospective design study. The first cohort (group 1; n = 25) received 4AC (A 60 mg/m^2, C 600 mg/m^2) and the second cohort (group 2; n = 50) received 5FEC (F 500 mg/m^2, E 90 mg/m^2, C 500 mg/m^2) adjuvant polychemotherapy. Both groups completed an 18-week high intensity strength training program. Outcome measures were; changes in quality of life (EORTC-QLQ-C30, MFI-20), muscular strength (one-repetition maximum; leg press) and cardiopulmonary function (VO2max) between baseline and follow-up.
Results: Baseline characteristics were similar in both groups. After completing the 18-week training program, the 75 subjects as a group showed a significant improvement in all outcome measures. No significant differences, in changes of the EORTC-QLQ-C30 and MFI-20, one repetition maximum of the leg press and the VO2max between the two groups, were demonstrated.
Conclusion: After adaptation of the Dutch national breast cancer treatment guidelines, patients received prolonged and increased dose of anthracyclines. This however did not result in a difference in baseline situation before rehabilitation and in training response nor in quality of life between the two groups. This preliminary survey suggests that this guideline adaptation, based on improved survival, does not affect the physical condition of the patient.

1138 POSTER

Development and evaluation of an evidence-based DVD for cancer survivors (CS) at treatment completion

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Background: Many CS have ongoing physical, emotional and psychological sequelae following treatment for cancer. We developed a DVD for CS at the time of treatment completion to assist psychological adjustment/rehabilitation.
Methods: A multidisciplinary team (including CS) was formed. We conducted a literature review (LR) and focus groups (FG) with CS and health professionals (HP). Results from the LR and FG informed the structure and content of the DVD as well as filmed interviews with CS. Interviews were edited to fit the required structure. Two HP provided additional content. Drafts were reviewed for clarity and accuracy. Evaluation with CS and HP asked participants to rate each section of the DVD and assessed views regarding style, length, format, relevance and perceived usefulness.
Results: Three FG involved 22 CS with a diverse range of backgrounds. Four FG involved 20 HP. Qualitative analysis revealed 12 broad categories/themes. Most common issues identified by both CS and HP were: managing fatigue; anxiety about recurrence; others expecting you to be back to normal; new expectations about physical ability, and anxiety about leaving the system. All themes from the FG and evidence from the LR were included in the DVD. The final 52-minute DVD comprises interviews with 14 CS and 2 HP. 33 CS (15 male) evaluated the DVD. Cancer types included breast, prostate, bowel, lung and lymphoma. 116 HP reviewed the DVD [medical (47%), nursing (23%), radiation therapy (21%), allied health (10%)]. Minor modifications were made in response to the evaluation. The majority of CS and HP agreed or strongly agreed that the DVD was informative (>95%), easy to understand (100%) and would be reassuring for survivors (>90%). CS felt the DVD would help others to feel more in control (>80%), know what to expect (>80%) and feel less anxious (>75%). Over 95% of HP believed the DVD was relevant to the circumstances of CS. Respondents reported a lack of other information for CS and frequently suggested the DVD contained important new information.
Conclusions: This is an inexpensive resource that is highly valued by CS and HP and should be made available to all people treated with curative intent, around the time of treatment completion.

1139 POSTER

Treatment patterns and patient characteristics associated with treatment for chemotherapy-induced anaemia in community-based oncology practices in the U.S.

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Background: EDUCATE (EDUcating Clinicians to Achieve Treatment guideline Effectiveness) is a year-long educational intervention study among US health care providers involving guideline adherence in chemotherapy induced anemia (CIA). This analysis using baseline data prior to the educational intervention was designed to examine CIA treatment patterns and patient characteristics associated with receiving CIA treatment in patients for whom treatment was recommended and those where immediate treatment was not required.
Methods: Medical records of adult cancer chemotherapy patients (sequential sample, 2005−06) were abstracted at 47 sites. We identified 484 CIA patients for whom guidelines recommend treatment with either erythropoiesis stimulating agents (ESAs) or transfusion (hemoglobin [Hb] < 11 g/dL or Hb 11−12 g/dL and anemia symptoms/risk factors) and 908 patients for whom immediate treatment was not required. Data elements included demographics (age, gender), cancer type and duration, Hb, anemia symptoms (fatigue, dizziness, edema, chest pain, tachycardia), and risk factors (prior transfusion, radiation/chemotherapy, COPD, cardiac/cerebrovascular disease). Multivariate logistic regression included variables associated with CIA treatment at $p < 0.2$ in bivariate analyses. Adjusted odds ratios (AOR) and 95% confidence intervals (CI) are presented.

Results: In patients for whom treatment was recommended, 54% (263/484) received treatment. In patients for whom immediate treatment was not required, 14% (124/908) were treated with an ESA or transfusion. Among patients for whom treatment was recommended, patients with colorectal cancer (AOR = 0.36, 95% CI=0.17−0.77) and lymphoma (AOR = 0.40, 95% CI=0.17−0.93) were less likely to receive treatment than patients with other cancers, adjusting for age, Hb, prior transfusion, prior chemotherapy, COPD, cardiac disease, fatigue, and cancer duration. Furthermore, in the same multivariate model, patients with lower Hb were more likely to receive treatment (p = 0.004). Among patients for whom immediate treatment was not required, no differences in patient characteristics were found between those who were and were not treated.
Conclusions: Transfusions and ESAs were only administered to 54% of patients where guidelines recommend treatment. Cancer type and lower hemoglobin were associated with receiving a transfusion or ESA among patients for whom CIA treatment was recommended.

1140 POSTER

Epoetin beta therapy in anemic patients with solid tumor or non myeloid hematological malignancies receiving chemotherapy: results of a large prospective cohort study

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Background: Anemia is the most frequent hematological complication of cancer patients (pts) receiving chemotherapy. The efficacy of epoetin beta (E) is well documented in clinical trials in anemic cancer pts. This study was conducted to assess E use, efficacy, safety and impact on quality of life (QOL) in cancer pts, in routine practice.
Methods: This prospective, multicenter, longitudinal, observational French cohort assessed a 4-month follow-up of informed consent cancer pts (including both solid tumors [ST] and non myeloid hematological malignancies [H]) treated with E for chemotherapy-related anemia. Patients were included between January 2005 and March 2006. The response was defined
as an Hb increase of $\geqslant$2 g/dl and/or an achievement of Hb value $\geqslant$12 g/dl without any blood transfusion after E treatment initiation. QOL was assessed by FACT scale.
Results: Among 3256 pts enrolled in 423 centres, 2880 were analysed: 75% of pts had a ST (lung: 30%; breast: 20%) and 25% had a H (non-Hodgkin lymphoma 51%; multiple myeloma 31%). Pts' characteristics were: mean age 63$\pm$12 yrs, male 50%, performance status 0 (13%), 1 (46%), $\geqslant$2 (41%). The median time from diagnosis to inclusion was 5 months. 52% of pts received their first line of chemotherapy and 25% their second one. 44% of pts (56% of ST and 9% of H) received platinum based regimen. 26% of pts received prior radiotherapy. 12% of pts had a past history of EPO administration. At inclusion, Hb levels were distributed as: 19% <9 g/dl, 66% [9−11[g/dl, 15% [11−13[g/dl. Endogenous erythropoietin concentration was controlled in only 2% of pts, ferritin in 17% of pts, transferrin saturation in 12% and reticulocytes in 11%. At initiation, 98% of pts received a median dose of 30000 U/week of E on a once weekly regimen schedule. Iron supplementation was given in 49% (3% IV) of ST and 13% of H pts. 21% of pts (18% of ST and 31% of H) received at least one blood transfusion during the study. Median Hb level at baseline was 10.1 g/dl [95CI 10−10.1] in ST and 9.6 g/dl [95CI 9.4−9.6] in H. Hb RR was 54.8% [95CI 52.6−56.9%], 54.5% in ST and 56.1% in H. In multivariate analysis, gender, PS, number of prior lines of chemotherapy, platinum based regimen and iron supplementation were identified as predictive factors of response. The mean of FACT score improved from 27.5 [95CI 27−28] at initiation to 31.3 [95CI 31−32] at the end of study (p < 0.001). Thromboembolic events were reported for 1.9% of patients.
Conclusion: this large prospective cohort study confirms the efficacy and safety of epoetin beta and its positive impact on QOL in routine practice treatment of anemic cancer patients. The study also shows very few biological tests were done before initiation of E in routine practice.

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Evaluation of extended dosing intervals versus weekly dosing of darbepoetin alfa (DA): A phase 2 study in cancer patients (pts) with chemotherapy-induced anemia (CIA)

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Background: Being able to treat CIA with erythropoiesis-stimulating agents like DA on the same schedule as chemotherapy (CTX) regimens could benefit pts by reducing clinic visits.
Materials and Methods: This was a phase 2, 25-week (wk), open-label study to evaluate noninferiority of DA in pts with CIA who were randomized 1:1 to either an extended dose schedule (DA-EDS) group (DA 300 mcg Q2W if CTX was QW, Q2W, or Q4W or DA 500mcg Q3W if CTX was Q3W) or a weekly DA (DA-QW) group (150 mcg QW regardless of CTX schedule). Stratification factors were CTX cycle length, screening hemoglobin (Hb) (<10 vs $\geqslant$10 g/dL), and type (lung/gynecological vs other cancers). The primary endpoint was change in Hb from baseline (BL) to wk 13.
Results: The analysis included all randomized pts (374 DA-QW pts; 378 DA-EDS pts) who received $\geqslant$1dose of DA. Demographics were broadly similar, DA-QW vs DA-EDS (median age, 63 vs 64 years; 32% vs 35%, lung/gynecological cancer; 78% vs 75%, disease stage III/IV.) Results are shown (Table). There was no difference between DA-EDS and DA-QW in mean change in Hb (BL to wk 13) (95% CL: −0.3, 0.2), with an upper limit $\leqslant$0.75g/dL supporting the noninferiority of the DA-EDS arm. The %pts with Hb $\geqslant$11g/dL by Kaplan-Meier estimates was also similar (difference [95% CL] = 1 [−3, 6]). Adverse events were similar between the groups, DA-QW vs DA-EDS, 23 (6%) vs 21 (6%) with thromboembolic events, 4 (1%) vs 5 (1%) with myocardial infarction or coronary artery disease, and 39 (10%) pts in each arm died.
Conclusions: In this study, DA, when administered synchronized with CTX schedules, appeared to be efficacious with no unexpected adverse events. This study provides the first prospective data on how the multiple dosing regimens available with DA can be paired with chemotherapy administered across a range of dosing schedules.

Table

	DA-QW n = 374	DA-EDS n = 378
Mean (SD) BL Hb, g/dL	10.1 (0.9)	10.1(0.8)
Mean* (SE) change in Hb, g/dL – BL to wk 13 [n]	0.9 (0.08) [374]	0.9 (0.08) [375]
KM% (95%CL) pts who achieved Hb $\geqslant$ 11 g/dL – BL to EOS [n]	94 (90, 98) [323]	94 (91, 98) [334]
KM median time to achieve Hb $\geqslant$ 11 g/dL – BL to EOS [n]	7.0 (6.0, 8.0) [323]	7.0 (7.0, 9.0) [334]
KM% (95%CL) pts who had TFNs – BL to EOS [n]	29 (24, 34) [374]	26 (21, 30) [378]
Pts who had treatment-related adverse events, n (%)	18(5)	14(4)

*Least squares mean, last value carried forward; SD = standard deviation; BL = baseline; Hb = hemoglobin; CL = confidence limit; KM = Kaplan-Meier; TFN = transfusion.

1142 POSTER

Breakthrough pain in cancer patients: assessment and treatment by four specialities in five European countries

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Background: To gain in-depth understanding of the incidence and treatment of breakthrough pain (BTP) in cancer patients, market research was undertaken in France, Germany, Italy, Spain and UK, among four clinical specialities.
Methodology: A total of 483 oncologists, GPs, palliative care, and pain specialists surveyed on their involvement in cancer patients with BTP and approaches to treatment.
Results: Among cancer patients treated by oncology specialists in the previous year approximately one quarter had died. Of these ~60% were estimated to have experienced chronic pain and 40% as having an average of ~4 episodes of BTP/day for a total of 28 days. In contrast, for cancer patients who had died in the past year seen by GPs and pain specialists,