5-hydroxytryptamine-3 (5-HT3) serotonin receptor antagonist, dexamethasone (DEX), and aprepitant is recommended before chemotherapy of high emetic risk. 5-HT3 serotonin receptor antagonist has been great benefit in the prevention of acute emesis, especially for moderate to high emetogenic chemotherapy. Granisetron (GRN) is one of the worldwide used 5-HT3 serotonin receptor antagonists. 1 mg or 0.01 mg/kg GRN dose is recommended by antiemetic guidelines. In Japan, high dose GRN (3 mg) combined with DEX is routinely used, aprepitant has not been approved yet. We conducted randomized controlled trial to compare the two different doses of GRN (3 mg VS 1 mg) in prevention from acute emesis.
Material and Methods: Patients who receiving moderate or high emetogenic chemotherapy in Japan were randomly assigned to GRN 3 mg (arm A) or 1 mg (arm B) with adequate amount of DEX according to emetic risk category. Patients were stratified according to previous history of chemotherapy, regimen (cisplatin containing or not) and institutions. Primary endpoint was proportion of patients with complete response (defined as no vomiting episodes and no use of rescue medication) in the first 24 hours after chemotherapy. Non-inferiority margin was predefined in this study protocol as a 15% difference between groups in the proportion of patients with complete response. This study is registered with UMIN, number UMIN000000984.
Result: From January 2008 to January 2009, 365 patients from 10 medical centers were recruited. 183 patients were assigned to arm A and 182 to arm B. In the first 24 hours after chemotherapy, complete response was achieved by 90 and 88 percent of patients, respectively. Non-inferiority was proven statistically. In subgroup analysis, no favorable trend was detected. Antiemetic treatment was equally well tolerated, and no significant difference was found in the incidence of adverse events.
Conclusions: GRN 1 mg combined with DEX is not inferior to 3 mg combined with DEX for the prevention of acute emesis induced by moderate or high emetogenic chemotherapy. Our study confirms no differences in both groups. We think this is the first randomized controlled trial, presenting non-inferiority between 3 mg and 1 mg GRN statistically. Consequently, 1 mg dose of GRN combined with DEX should be considered the most appropriate prophylactic regimen for the prevention of acute emesis.

3081 POSTER

Reduced therapy-related fatigue in mice with nab-paclitaxel as compared with Cremophor-based paclitaxel

L.A. Toth[1], M.A. Ray[1], R.A. Trammell[1], S. Ran[2]. *[1]Southern Illinois University School of Medicine, Department of Pharmacology, Springfield IL, USA; [2]Southern Illinois University School of Medicine, Department of Medical Microbiology Immunology & Cell Biology, Springfield IL, USA*

Background: The frequent occurrence of fatigue in cancer patients and survivors negatively impacts the quality of life and clinical outcome. *Nab*-paclitaxel (Abraxane®) is an albumin-bound 130-nm particle form of paclitaxel that demonstrated higher efficacy and was well tolerated compared to Cremophor EL-based paclitaxel (Taxol®) in clinical trials for metastatic breast cancer. In this study, we developed a mouse model for quantifying fatigue and objectively compared fatigue induced by Abraxane and Taxol.
Materials and Methods: Female BALBIcJ mice were implanted with a telemetry device that transmitted information on both core temperature and horizontal locomotor activity. Activity, wheel running, temperature, food intake, and body weight were monitored before, during, and after administration of Taxol or Abraxane (10 mg/kg iv, qd × 5; n = 9/group). To determine the potential causes of chemotherapy-induced fatigue, measurements were conducted for the levels of proinflammatory cytokines, anemia, general debilitation, neuromuscular impairment, and sleep disturbance.
Results: Taxol and Abraxane both reduced horizontal locomotor activity and wheel running in mice. With either drug, mice showed essentially normal activity during the first two hours of the dark phase. However, activity fell below normal for both measures in the remainder of the dark phase during the drug administration and the first week after chemotherapy. Mice treated with Abraxane resumed normal amounts of dark-phase activity 2 weeks after treatment, whereas mice treated with Taxol remained depressed until week 4 after treatment. During periods of fatigue, mice did not show anemia, elevated serum concentrations of proinflammatory sleep-modulatory cytokines, or disturbed sleep. However, mild general debilitation (i.e., weight loss, anorexia, and hypothermia) and mild neuromuscular impairment were observed.
Conclusions: This study provides a reliable model for quantatively measuring chemotherapy-induced fatigue. The combined assessment of running wheel activity and horizontal locomotor activity demonstrated that mice treated with taxane chemotherapy developed fatigue. Compared with Taxol, Abraxane treatment resulted in less fatigue and a faster recovery, potentially due to its rapid tissue distribution and the absence of toxic solvents. These observations are consistent with clinical data for Abraxane which shows a more rapid resolution of peripheral neuropathy compared with Taxol.

3082 POSTER

Efficacy of a survaillance dental programm on prevention of osteonecrosis of the jaw in cancer patients with bone metastases: a single institution preliminary experience

L. Bonomi[1], A. Bettini[1], R. Bonacina[2], F. Villa[2], U. Mariani[3], E. Rota Caremoli[1], C. Tondini[1]. *[1]Ospedali Riuniti Bergamo, Oncology, Bergamo, Italy; [2]Ospedali Riuniti Bergamo, Dental, Bergamo, Italy; [3]Ospedali Riuniti Bergamo, Oral pathology, Bergamo, Italy*

Background: osteonecrosis of the jaw (ONJ) is a dismal event associated with bisphosphonates (BPs) therapy for cancer patients with bone metastases (BM). We designed a preventive dental programme during or prior to BPs therapy to attempt a reduction in the risk of ONJ.
Patients and Methods: Starting from February 2007 through February 2009, 137 consecutive cancer patients with BM scheduled for BPs therapy (zoledronic acid, pamidronate or ibandronate) were prospectively offered an educational training on oral hygiene and an odontoiatric evaluation (dental visit and orthopantomography of the jaw) to detect odontoiatric risk factors and treat them, both at baseline and every six months afterwards. 46 patients (33.6%) had already received a median of 7 monthly BPs (range 1−48) at the time of baseline evaluation, while 91 patients (66.4%) had not yet been treated. Both groups of patients were offered the same preventive programme.
Results: Overall, the total patient population received median of 8 months of BPs (range 1- 48): 12 months (range 1- 48) for the pretreated and 5 (range 1−23) for the not-pretreated population of patients, respectively. Only two cases of ONJ were described, both in the pretreated group. The first one was diagnosed after 3 cycles of zoledronic acid and was related to a recent dental avulsion. Of note, this patient had been treated with risendronate for a long period for osteoporosis just before the development of BM. The other case was observed after 7 cycles of zoledronic acid in a patient with BM from kidney cancer while on concomitant treatment with sunitinib. Because there are some evidences that anti-angiogenic therapies may increased ONJ risk, we cannot exclude an interaction of the therapy with preexisting risk factors.
Conclusions: Our prospective single-institution experience of systematic adoption of a preventive dental programme for patients scheduled to undergo BPs therapy for BM seems to confirm reported literature evidence of the importance of odontoiatric evaluation and treatment before starting BPs therapy in reducing the risk of ONJ.

3083 POSTER

Patients experience with treatments of chemotherapy induced anemia (CIA) and myelodysplastic syndromes (MDS)

Z. Cong[1], A. Ireland[2], D. Stull[2], N. McGarvey[3], A. Brooks[2], L. Kleinman[2]. *[1]Amgen Inc, Global Health Economics, Thousand Oaks CA, USA; [2]United BioSource Corporation, Center for Health Outcomes Research, Bethesda MD, USA; [3]University of California Los Angeles, School of Public Health, Los Angeles CA, USA*

Background: Anemia, a common hematologic complication of cancer and cytotoxic treatments, is often treated with erythropoiesis stimulating agents (ESAs) and red blood cell (RBC) transfusions. While some studies have explored patient treatment experience (e.g., routine disruption, and emotional/social strain), gaps remain in the literature. The objective of this study was to assess anemia treatment experiences from patients' perspectives and to explore potential concepts for inclusion in new anemia treatment experience instruments.
Material and Methods: Focus groups and individual interviews were conducted with adult patients with CIA or MDS receiving ESAs and/or RBC transfusions within 28 days prior to interview. Domains explored in the discussion guide included administration pain/discomfort, temporal effects, treatment outcomes, out of pocket (OOP) expenses, effects on employment, and social support. Transcripts were coded and qualitatively analyzed with Atlas.Ti. Sociodemographic and clinical information was collected through questionnaires and analyzed descriptively.
Results: 6 focus groups and 10 individual interviews were conducted with 28 patients (mean age: 68, SD age: 12, female: 54%, CIA: 50%, MDS: 50%, ESA only: 57%, ESA and transfusion: 43%).
Patients mentioned temporary stinging or burning sensation from ESA and discomfort of keeping their arms in a specific position during transfusion. Timing and location issues were discussed. Many CIA patients received ESAs on the same day and at the same clinical site as chemotherapy. All transfusions received by CIA patients were on different days than chemotherapy. On average, ESAs took less than 1 minute to administer and the entire visits took less than 1 hour. Transfusion patients had blood cross-matched at least 1 day before treatment and transfusions took 6+ hours to complete. As for treatment effects, patients focused on how quickly they