

correlation between intensity of symptoms and clinical evidence. Probably we need a new assessment scale of OM for target therapy.

3070

POSTER

Bone pain reduction by intense bisphosphonate therapy in patients with newly diagnosed bone metastases

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Background: In many cases of severe bone pain caused by bone metastases the standard pain therapy is insufficient and accompanied with serious side effects. Clinical trials have demonstrated that bisphosphonates can provide effective and sustained relief from bone pain by using long-term standard administration. Particularly during the first weeks of a metastatic bone disease it is important to reduce pain in order to maintain quality of life and the courage of the patient.

Materials and Methods: 17 patients (breast cancer n = 11, lung cancer n = 3, renal cell cancer n = 3) with newly occurred osteolytic skeletal metastases and bone pain received intensified (loading-dose) ibandronate treatment right after diagnosis of bone metastases. They were treated with intravenous ibandronate 6 mg infused over 1 hour on 3 consecutive days. All patients were previously untreated with bisphosphonates and received only symptomatic pain therapy (NSAR, analgesics, opioids). The bone pain severity was rated on a daily basis by the patients using a visual analog scale (VAS, range: 0 (no pain) to 10 (maximum pain)). Within 3 weeks all patients received further therapy (e. g. radiation, surgery, chemotherapy).

Results: Loading-dose ibandronate therapy significantly reduced bone pain in 15 patients within the first 5 to 7 days (VAS day 0: 6–7 vs. day 7: 3–4). There was no increase in pain medication. Only 2 patients showed no response concerning a distinct pain reduction within the first days of therapy.

Conclusions: This small pilot study demonstrated that the administration of loading-dose ibandronate resulted in a rapid reduction of bone pain within the first days after diagnosis of bone metastases. This dosing schedule intensifies the already proven analgesic effect of bisphosphonates, possibly by suppressing the pathological processes of osteoclast-associated bone destruction. Based on these results a controlled clinical trial should be carried out to further investigate and prove the effects of a loading-dose ibandronate therapy.

3071

POSTER

Can oncology nurses and other allied health professionals learn to treat post traumatic stress disorder in cancer survivors

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Post traumatic stress disorder (PTSD) as defined by the American Psychiatric Association's diagnostic and statistical manual of mental disorders (DSM-IV) is now a recognized phenomenon in cancer survivors. In the UK the National Institute for Clinical Excellence (NICE) advises using trauma focused therapy to treat PTSD, however a shortage of suitably trained psychologists (Price et al. 2006) makes access to appropriate psychological services difficult.

In January 2008 we established a clinic, offering assessment and treatment to cancer survivors reporting symptoms of post traumatic stress. Apart from offering treatment to these patients the aims of the clinic were to explore if stress following a cancer diagnosis is the same as stress following other traumas, do they respond to trauma focused therapy and can nurses and other allied health professionals. The clinics were conducted by a Clinical Psychologist specialising in post traumatic stress and a Nurse Consultant in medical oncology.

During the first year the clinic was run 22 patients were assessed for treatment.

We have found that PTSD following diagnosis and treatment of cancer may be difficult to diagnose. The trauma is not always easily identifiable. There may be multiple traumas and also other psychological conditions, caused by the treatment and diagnosis, which need to be treated before the PTSD is treated. There is also the problem of fear of recurrence and helping patients live with uncertainty. However once the diagnosis has been made and a treatment plan devised, selected patients were successfully treated by the nurse under the supervision of the Clinical Psychologist.

We have shown the PTSD in this group of patients can be successfully treated using trauma focused therapy and other cognitive behavioral methods. The diagnosis may be difficult to make as the trauma may be difficult to identify, or there may be multiple traumas. There may also be coexisting psychological conditions caused by the diagnosis or treatment

which require treating before the PTSD. We feel that the skills of a clinical psychologist are still required to diagnose, develop a treatment plan, provide clinical supervision for nurses and treat more complicated cases. Once diagnosed, suitably trained nurses and allied health professionals can treat these patient under supervision. We have developed a hub and spoke model for the education and supervision of nurses and other professionals to treat PTSD in cancer survivors.

3072

POSTER

Palonosetron plus a three-day aprepitant and dexamethasone schedule to prevent nausea and vomiting in patients receiving highly emetogenic chemotherapy

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Background: 5-HT₃ receptor antagonists (5-HT₃-ra) plus dexamethasone significantly improve acute chemotherapy-induced nausea and vomiting (CINV) in highly emetogenic chemotherapy (HEC). The NK-1 receptor antagonist aprepitant has also been approved for both acute and delayed CINV in a three-drug combination. The aim of this study was to evaluate the efficacy of 5-HT₃-ra palonosetron plus a 3-day aprepitant and dexamethasone schedule in the prevention of HEC-related CINV.

Patients and Methods: Eligible pts were chemotherapy-naïve adults receiving HEC since 2007 (n = 182). Palonosetron i.v. 0.25 mg, dexamethasone i.v. 20 mg and aprepitant p.o. 125 mg were administered 1-hour before chemotherapy. Aprepitant p.o. 80 mg and dexamethasone p.o. 4 mg were administered on days 2–3. Rescue therapy was metoclopramide i.m. 10 mg plus dexamethasone i.m. 4 mg. Primary endpoints were complete response (CR), measured as no CINV in days 1 to 5 and no rescue therapy, and complete control of nausea and vomiting (CC: CR and no more than mild nausea); secondary endpoint was quality of life (QoL) evaluation. CC and CR were assessed during acute (0–24 h), delayed (25–168 h) and overall (0–168 h) period. QoL was evaluated prior to each cycle with an EORTC QLQ-30 questionnaire.

Results: 84% of pts achieved CR early (at the first cycle). In the early no-CR pts, CINV was the same (98%) in the following cycles. During the acute phase 91% and 99% of pts achieved CR and CC, respectively; in the delayed phase we reported 85% CR and 97% CC; in the overall period 77% of pts achieved CR and 96% CC. The impaired QoL parameters in pts who experienced CINV were fatigue (41% of pts), pain (23%), social activities (33%).

Conclusions: These results confirm the efficacy of palonosetron in combination with aprepitant and dexamethasone to prevent both acute and delayed HEC-related CINV. Moreover, the three-drug combination seems to improve pts' QoL. Pts who achieve an early CR keep it for the following cycles, experiencing better compliance to chemotherapy and QoL.

3073

POSTER

Quality of life in patients with gastric cancer: psychometric properties of the Iranian version of the EORTC QLQ-STO22

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Background: Disease and treatment related events, can adversely affect the quality of life of patients with cancer. The purpose of this study was to translate and validate a gastric cancer specific health related quality of life questionnaire (EORTC QLQ-STO22) for Iranian patients suffering from gastric cancer.

Material and Methods: Forward-backward procedure was applied to translate the English language version of the EORTC QLQ-STO22 into Persian (Iranian language). Then, the questionnaire and the EORTC core quality of life instrument (QLQ-C30) were administered to a sample of patients with confirmed diagnosis of gastric cancer. All patients filled in questionnaires before and after one month of treatment. Patients were divided into two groups based on intension of treatment (curative vs. palliative). Reliability and validity of the module was tested by internal consistency and known group comparisons, respectively.

Results: In all 105 patients were entered into the study. Cronbach's alpha for multi-item scales (to test reliability) ranged from 0.54 to 0.87. The questionnaire discriminated well between clinically distinct subgroups of patients both before and after treatment.

Conclusion: In general, the Iranian version of the EORTC QLQ-STO22 demonstrated a good reliability and clinical validity to support its use in combination with core questionnaire in outcome studies of gastric cancer in Iran. However, using the QLQ-STO22 in a wide range of Iranian patients

with gastric cancer should allow further confirmation of its psychometric properties.

3074

POSTER

Darbepoetin alfa for the treatment of chemotherapy-induced anemia in patients with solid tumors

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Background: Chemotherapy-induced anemia is a frequent problem in cancer patients (pts) and could be treated with erythropoiesis stimulating agents (ESAs). Among ESAs, darbepoetin alfa (DA) is a distinct molecule with a unique molecular structure and a much longer plasma half life than recombinant human erythropoietins (rHuEPO). This study in daily clinical practice conditions assesses the pattern of use and effect of DA in patients with solid tumors.

Material and Methods: This was an observational, retrospective, multicenter study performed in 58 medical oncology and hematology departments in Spain. Eligible pts were ≥ 18 yrs, diagnosed of non-myeloid malignancies and treated with chemotherapy (CT) and DA from October 2005 to October 2006. Data on demographic and clinical characteristics, CT and radiotherapy (RT), DA administration, blood transfusions, and hemoglobin (Hb) levels were collected from DA treatment initiation up to a maximum of 16 weeks or until treatment discontinuation. We report the results for the group of pts with solid tumors.

Results: A total of 498 pts with solid tumors were included in this study. Median age was 62.0 years (range: 18.5–85.0), 50.8% were women, 76.9% had ECOG status 0–1, 49.4% had IV stage cancer, and 58.8% had not received prior CT. Lung (23.1%), breast (22.5%) and gastrointestinal (21.3%) were the most common tumour types. At DA initiation, mean Hb was 10.1 g/dL (SD 1.0) with most of the patients (71.7%) starting DA treatment with baseline Hb between 9–11 g/dL. Administration of DA was mainly every three weeks (60.2%). Regarding where the drug was administered, 60.4% was in the day-care unit and 25.1% at home. Auto-administration only occurs in 10.4% of the pts. Mean DA treatment duration was 10.9 weeks (SD 4.21) with a mean weekly dose of 162.6 mcg (SD 31.3). The proportion of pts who achieved Hb ≥ 11 g/dL was 64.8% (95% CI 60.0–69.6). A total of 56 pts (11.6%) required RBC transfusions from week 5 to end of treatment. Adverse reaction (AE) potentially related to DA were reported in 3.4% of pts (17 pts) and only in 3 cases DA was withdrawn.

Conclusions: Results from this clinical practice study suggest that the use of DA in patients with solid tumors is an effective and well-tolerated treatment for CIA.

3075

POSTER

Thrombocytopenia (TCP) in adult cancer patients receiving cytotoxic chemotherapy: incidence and relative risk estimates from a retrospective hospital-based cohort study

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Background: TCP is a well-known side effect of most cytotoxic drugs, though the incidence estimates from daily clinical practice are scarce. We aimed to determine the incidence and relative risk (RR) of chemotherapy-induced TCP in adult patients with solid tumors.

Material and Methods: Patients receiving standard chemotherapy at University Medical Center (UMC) Utrecht from 2004–2006 were identified from the Utrecht Patient Oriented Database (UPOD) and the Regional Cancer Registry Middle Netherlands in this single-center retrospective cohort study. The aim of this study is to determine the incidence of (a) overall TCP (platelet count $<100 \times 10^9/L$ at any time during the first

course of chemotherapy) as well its grade according to the NCI-CTC criteria v 3; (b) TCP occurring with or without other cytopenias; (c) the incidence and RR of TCP associated with different cytotoxic agents (used as monotherapy or in combination).

Results: 614 patients receiving 19 different cytotoxic agents in 39 different regimens were identified. The incidence of overall TCP was 21.8%. Grade 1, 2, 3, and 4 TCP occurred in 9.9%, 5.0%, 3.6%, and 3.3% of patients, respectively. The incidence of TCP without other cytopenias was 6.2%. The highest incidences of TCP occurred in patients receiving carboplatin monotherapy (81.8%), carboplatin combination therapy (58.2%), gemcitabine combination therapy (64.4%) and paclitaxel combination therapy (59.3%). The highest RR of TCP, compared to cisplatin based therapy (the most commonly used regimen), was observed for combination therapy of carboplatin/gemcitabine (RR 10.1, 95% CI 5.5–18.5) and for combination therapy of carboplatin/paclitaxel/etoposide (RR 11.8, 95% CI 6.7–20.8). The highest incidences of TCP without other cytopenias were observed in combination therapies including oxaliplatin (28.6%) and gemcitabine (28.9%).

Conclusions: In daily clinical practice, TCP was observed in approximately one of five cancer patients receiving chemotherapy. Regimens with carboplatin, gemcitabine and paclitaxel are associated with the highest risk of TCP. Further research is needed to investigate the underlying mechanisms and clinical consequences of chemotherapy-induced TCP.

3076

POSTER

Comparison of the protective effects of melatonin and octreotide on radiation-induced intestinal injury

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Background: The protective effects of melatonin and octreotide on normal tissues were demonstrated in various studies. However there is no randomized study comparing the potency of melatonin and octreotide for protection of radiation enteritis (RE). To the best of our knowledge, this is the first study comparing the effects of melatonin and octreotide, which are known to be potent antioxidants, in protecting the radiation enteritis.

Methods and Materials: For this study, 42 male 3-month-old Swiss albino mice weighing 40 ± 10 g were used. All 42 mice were matched according to body weight and randomly assigned to one of six groups: group C: control group; group R: RT alone; group M: melatonin (15 mg/kg, i.p.), and group MR: melatonin + RT; group O: octreotide (50 μ g/kg i.p.) and group OR: octreotide + RT. The radiation dose was 8 Gy to whole body with single dose which has been shown to produce significant intestinal injury.

Results: All mice tolerated the experiments and no radiation or drug-related deaths occurred throughout the study. Non-irradiated-intestinal mucosal glands preserved their structure. In histological evaluation, architectural disorganization including mononuclear inflammatory cell infiltration, congestion of blood vessels in the submucosa, and villitis is prominent, and also desquamation together with eosinophilic necrosis is seen in irradiated group. Mucosal thickness (MT), crypt height (CH), and villous height (VH) are all diminished following irradiation, and also a significant decrease in the number of goblet cells is seen. In the MR and OR groups, the villous pattern is well preserved, desquamation at villous tips and edema is prominent, but necrosis is absent. Melatonin and octreotide treatment prior to irradiation prevented the decrease in the MT (1.04 ± 0.15 mm; $p < 0.001$ and 0.86 ± 0.15 mm; $p = 0.01$). However pre-irradiation melatonin significantly preserves MT compared to pre-irradiation octreotide ($p = 0.05$), respectively. The VH (0.59 ± 0.17 mm vs. 0.30 ± 0.06 ; $p = 0.009$) and CH (0.34 ± 0.07 vs. 0.26 ± 0.05 mm; $p = 0.03$) were significantly preserved in Group MR compared to Group R. The difference in VH and CH between Group MR and OR did not differ significantly ($p = 0.86$). Pre-irradiation octreotide did not significantly preserve VH ($p = 0.07$) and CH ($p = 0.14$).

Conclusion: Melatonin and octreotide are potent agents for protection of RE. But melatonin significantly preserves the histological structure of the intestines of the mice compared to octreotide, which should be warranted with clinical studies.