

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

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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 Adverse reaction (AE) potentially related to DA were reported in 3.4% of pts (17 pts) and only in 3 cases DA was withdrawn.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.

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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.

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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.