

range within and across indications and were on average 4.18–4.78 times those for Botox in FD and HS and 2.41–3.18 times those for Botox in JCP (overall range 2.41–4.78).

Conclusions Botox and Dysport are not interchangeable. The doses used in Poland are consistent with the results of the REAL DOSE study [1]. Treatment is individualised according to patient needs, experience and doctors' preferences.

Reference

1. Marchetti A *et al*, Retrospective evaluation of the dose of Dysport and Botox in the clinical management of cervical dystonia or blepharospasm (The REAL DOSE Study), *Movement Disorders* Vol. 20, No. 8, 2005, pp. 937–944

No conflict of interest.

DGI-076 USE OF COLONY STIMULATING FACTORS (CSF-G) IN FEBRILE NEUTROPENIA IN PATIENTS UNDERGOING CANCER CHEMOTHERAPY

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Background The hematopoietic growth factors are a fundamental tool for medical oncologists in the treatment of chemotherapy-induced cytopenia. The proper use of these therapeutic aids plays an important role in terms of reduction of morbidity, mortality and costs.

Purpose To evaluate whether clinical practise follows national guidelines on colony stimulating factors (CSF-G) in the management of hematopoietic toxicity in oncology (AIOM 2010); to investigate the incidence of certain parameters involved in the overall assessment of the risk factors for febrile neutropenia (FN).

Materials and Methods In the first half of 2012, we analysed the CSF-G requirements in patients undergoing cancer chemotherapy. We selected patients treated with cancer chemotherapy, older than 60 years with a risk factor of FN > 20%, calculated on factors related to the chemotherapy regimen, patient age and type of tumour.

Results We identified 57 patients treated with chemotherapy and CSF-G. Of these, 27 were treated with lenograstim, 24 with pegfilgrastim and 6 with filgrastim. Evaluating the appropriateness of prescribing, according to the parameters identified, showed that only in 12 patients undergoing chemotherapy was a risk factor of FN greater than 20% observed; of these, 4 were treated with pegfilgrastim, 3 with lenograstim and 5 were not treated (3 of which were older than 65 years). We observed that most patients were treated for ovarian, breast or lung cancer or non-Hodgkin's lymphoma, whereas only a small percentage were treated for other cancers such as endometrial, colon, bladder, thymus or biliary tract cancer.

Conclusions The comparison between clinical practise and the AIOM guidelines showed that the use of CSF-G is higher than the level required by the guidelines, when referring exclusively to the 3 major risk factors considered. Therefore, the use of CSF-G in chemotherapy regimens with a low score for febrile neutropenia seems very influenced by additional factors related to the treatment, the patient and the disease.

No conflict of interest.

DGI-077 USE OF EVEROLIMUS IN COMBINATION WITH EXEMESTANE FOR THE TREATMENT OF ADVANCED BREAST CANCER IN A TERTIARY HOSPITAL

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Background Everolimus has recently been approved by the European Medicines Agency (EMA) for the treatment of postmenopausal women with advanced breast cancer in combination with exemestane, after treatment failure with letrozole or anastrozole. The approval was based on the results of the BOLERO-2 study.

Purpose To compare the use of everolimus plus exemestane in breast cancer in our hospital with the BOLERO-2 study.

Materials and Methods Retrospective study of all patients treated with everolimus in combination with exemestane from September 2011 to September 2012.

Data source: clinical history and Pharmacy Department records.

The following variables were analysed: age, disease stage, metastases and localization, previous treatment, adverse reactions, duration of treatment, discontinuation of treatment and reasons.

Safety was evaluated by the appearance of adverse reactions.

Results 9 patients with stage IV breast cancer were included. The median age was 54 (range 76–45) years. All patients had bone metastases and 2 had also visceral involvement (pulmonary and hepatic). Previous treatment included: letrozole/anastrozole (7), tamoxifen (6), fulvestrant (5) and chemotherapy (8). 5 patients met the inclusion criteria of the BOLERO-2 study.

The most frequent reason for discontinuation in the BOLERO-2 study was disease progression. In our study 7 patients discontinued, the reasons were: disease progression (3), death (2), and unknown (2). The median duration of treatment was 16 weeks (14.6 weeks in the BOLERO-2 study). 2 patients are still continuing with the treatment.

The main side effect was stomatitis (55.6%) as in the BOLERO-2 study. Other side effects in our study were: epistaxis, rash, fatigue, infection and gastrointestinal reactions.

Conclusions 55.55% of patients met the inclusion criteria of the BOLERO-2 study and the median duration of treatment was similar.

Stomatitis was the main adverse effect observed.

No conflict of interest.

DGI-078 USE OF SGN35 OR BRENTUXIMAB VEDOTIN IN ANAPLASTIC LARGE-CELL LYMPHOMA: A CASE REPORT IN PAEDIATRICS

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Background Lymphoma is one of the most frequent haemopathies among children and young adults. Anaplastic large cell lymphoma affects 15% of such children under 15 years old and 40% above 15 years old in France. Although the initial treatments are well codified and the efficacy of chemotherapy is well established in most patients, non-responses or relapses with these drugs are leading haemo-oncologists to look for new and effective therapeutic strategies. Thus, SGN35 or brentuximab vedotin is a monoclonal antibody drug conjugate (mADC). It combines an antibody that selectively targets CD30 expression in tumour cells and a cytotoxic drug derived from auristatin. This cell poison is delivered in situ and leads to apoptotic cell death. SGN35 activity is established in Hodgkin's lymphoma and relapsed or refractory systemic anaplastic large-cell lymphomas that are CD30+.

Purpose To report the use of brentuximab vedotin in a paediatric case study.

Materials and Methods A literature search was undertaken about the use of brentuximab vedotin in paediatrics. The pharmacy undertook the administrative work to obtain the treatment for the patient.

Results In July 2012, FDA licenced this ADC to treat CD30+ Hodgkin's lymphoma and relapsed or refractory systemic

anaplastic large-cell lymphoma in adults. It is currently awaiting conditional marketing authorization for adults in Europe. A Phase I/II study in paediatrics is at the moment recruiting. Brentuximab vedotin is administered every three weeks at 1.8 mg/kg (half-life ranges from 4 to 6 days and steady-state was achieved in 21 days for the ADC). Administration is possible in France, after the ANSM granted it temporary authorization on a named patient basis.

An 8-year-old male child, with a diagnosis of anaplastic large-cell lymphoma, was treated according to the ALCL99 protocol. Two months after diagnosis the tumour grew under this first-line chemotherapy. A multidisciplinary group decided to start brentuximab vedotin treatment. A total of 5 courses spaced 3-weekly were scheduled combined with chemotherapy. Signs of the tumour disappeared, thorax imaging normalised, fever and pulmonary and mediastinum adenopathies decreased.

Conclusions After the 4th dose of brentuximab vedotin, the treatment was well tolerated by the patient and the tumour regressed. Among adults, the median response is about 12 months. Thus, confirmation of efficacy still has to be evaluated. Further studies are required to establish the efficacy and safety profile in the paediatric population.

No conflict of interest.

DOI-079 VALPROIC ACID AND BEHAVIOUR DISORDERS: OBSERVATION OF EFFICIENCY AND TOXICITY IN A COGNITIVE-BEHAVIOURAL UNIT

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Background In order to limit neuroleptic use in the elderly, because of cardiovascular events, specialists in charge of behaviour disorders don't have many therapeutic options in cognitive-behavioural units (CBU).

Purpose Valproic acid (VPA) is an anticonvulsant and/or a mood stabiliser that can be used in a behavioural way in CBU. One side effect of VPA is hyperammonaemia, which can lead to sedation and changes in behaviour or personality.

Materials and Methods Inclusion criteria were opposition, agitation, aggressiveness or impulsiveness. Ammonia levels were assessed before starting the VPA, between 2 and 4 days and after 5 days with VPA. For each person included, Cockcroft's creatinine clearance, medical background and neuroleptic co-prescriptions were identified. Results are presented with mean \pm SEM.

Results The population was defined by an average age of 79.3 y \pm 1.74, a sex ratio of 15 men for 6 women; a creatinine clearance of 65.4 mL/min \pm 8.9, no patients had liver troubles or a history of epilepsy. 21 patients received VPA in the CBU, for at least one of the following indications: opposition (n = 9), agitation (n = 13), aggressiveness (n = 16) or impulsiveness (n = 6). 9/21 patients came out of the CBU with VPA (42.85%), 13/21 without VPA (61.9%), 5/21 with a neuroleptic (23.8%) and 8/21 without VPA or a neuroleptic (38.1%). Ammonia rates at D-1, between D2 and D4 and after D5 were respectively 47.47 μ M \pm 3.71, 51.4 μ M \pm 6.43 and 63.76 μ M \pm 4.95. Response rate to VPA was 55% (5/9 patients) for opposition, 37.5% (6/16) for aggressiveness, 38% (5/13) for agitation and 66.6% (4/6) for impulsiveness.

Conclusions Those results show that only one of every two patients with VPA were responders, and average ammonia increases during treatment. However, 100% of patients going out with VPA didn't have any neuroleptics and for 33%, VPA contributed to stopping neuroleptics.

No conflict of interest.

Pharmacotherapy: pharmacokinetics and pharmacodynamics (including: ADE, TDM, DUE)

PHC-001 AMIKACIN DOSING TO TREAT RESPIRATORY TRACT INFECTIONS ACCORDING TO PATIENT'S BODY MASS INDEX

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Background Body mass index (BMI) is a factor related to the disposition of aminoglycosides (AMG). Dosage is based on total body weight (TBW) or adjusted body weight (ABW) according to patients' BMI.

Purpose To assess if the amikacin dosage prescribed to patients matches with the dosage based on BMI.

To calculate the optimal cut-off point of BMI that predicts a 10% discrepancy between dosage based on TBW or ABW.

Materials and Methods Retrospective study January 2003–December 2010 performed in a 450-bed tertiary hospital.

Dosage of 15 mg/TBW was considered except for patients with TBW > 30% over ideal body weight (IBW). That dose was calculated according to ABW: $ABW(kg) = IBW + 0.4(TBW - IBW)$ as recommended.

Patients included: intravenous amikacin treatment of respiratory tract infections in an extended-interval dosing regimen with therapeutic drug monitoring of amikacin.

Patients excluded: <18 years, ClCr < 60 mL/min, sepsis, lack of data.

Data collected: demographics, TBW, height, BMI, renal function. Amikacin levels: fluorescence polarisation immunoassay (TDX, Abbott Lab)

Pharmacokinetic analysis: Bayesian estimation compartmental model (PKS programme)

Statistical analysis: ROC curve.

Results 133 patients (79.70% men). Mean (\pm SD): age: 62.12 years (\pm 15.48); TBW: 65.52kg (\pm 13.43); height: 166.89 cm (\pm 7.44); serum creatinine baseline: 0.68 (\pm 0.19) and CrCl: 97.32 mL/min (\pm 34.67).

Difference between TBW dose vs. ABW dose (mg)(%): BMI[<16]:16.45 vs. 16.45(0%); BMI[16–18.49]:16.57 vs. 16.57(0%); BMI[18.5–24.9]:15.28 vs. 15.61(2.2%); BMI[25–29.9]:12.70 vs. 14.30(11.2%); BMI[30–34.9]:11.56 vs. 14.34(19.3%); BMI[35–39.9] and [>40]: 1 patient.

A ROC curve was built to determine the best cut off point of BMI: 26 mg/m²

Difference between recommended dosage and prescribed dosage (mg): BMI[<16]: +1.45; BMI 16–18.49: +1.58; BMI[18.5–24.9]: +0.64; BMI[25–29.9]: –0.70; BMI[30–34.9]: –0.66; BMI[35–39.9] and [>40]: 1 patient.

Conclusions Considerable variation between the dosage of amikacin based on TBW and ABW was observed with a reduction of recommended dose in patients with BMI \geq 25 kg/m² and an overdose in patients with BMI < 24.9 kg/m².

A reduction of 10% or more of the adjusted calculated dose of amikacin was observed in patients with BMI \geq 26 kg/m².

No conflict of interest.

PHC-002 ANALYSIS OF THE INCIDENCE OF POTENTIAL DRUG INTERACTIONS IN HOSPITALISED PATIENTS

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Background Prescriptions with more than one drug increase the risk of drug-drug interactions, treatment failure, large pharmacological effects and adverse events.