

DOI-045 MANAGEMENT OF THE HAEMATOLOGICAL TOXICITY INDUCED BY BENDAMUSTINE

doi:10.1136/ejhp-2013-000276.311

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Background Bendamustine is approved in Spain for the treatment of chronic lymphocytic leukaemia (CLL), Non Hodgkin Lymphoma (NHL) and multiple myeloma (MM). The most frequent adverse reactions are haematological. Usually patients require supportive treatment with granulocyte colony-stimulating factors (G-CSF) for neutropenia and erythropoietins for anaemia.

Purpose To describe the approach to neutropenia and anaemia caused by bendamustine in patients diagnosed with NHL, CLL and MM in our Hospital

Materials and Methods Descriptive and retrospective study of patients treated with bendamustine between November 2008 and February 2012 in our hospital. We collected data on age, sex, diagnosis, neutrophils count and haemoglobin before treatment and after receiving bendamustine, the proportion of patients requiring G-CSF (filgrastim or pegfilgrastim) or erythropoietins (darbepoetin alfa). Average number of G-CSF and erythropoietins doses.

Results A total of 38 patients received bendamustine, of whom 13 were women and 25 were men, with a mean age of 67 years old. 28 patients were diagnosed with NHL, 4 with MM and 6 with LLC. Before treatment, the neutrophils count was 4,846/mm³ and haemoglobin 11.7 g/dL. Later these figures were 2,440/mm³ for neutrophils and haemoglobin 11 g/dL. 73.7% of patients required G-CSF and 10.5% erythropoietins. The median number of doses of G-CSF and darbepoetin alfa respectively were 6 and 2.5.

Conclusions Bendamustine appears well tolerated. Supportive treatment with G-CSF is required in the majority of patients to maintain neutrophil count. This is not the case for anaemia, which occurs less frequently, requiring less rescue treatment. However these patients require close monitoring during treatment.

No conflict of interest.

DOI-046 MONITORING OF ADHERENCE TO TREATMENT AND ADVERSE EVENTS IN THE MANAGEMENT OF PATIENTS WITH HIV INFECTION

doi:10.1136/ejhp-2013-000276.312

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Background Highly active antiretroviral treatment (HAART) is associated with improved health outcomes for people living with HIV/AIDS. Successful long-term treatment of HIV/AIDS requires near-perfect adherence to HAART. Constant monitoring of adherence to HAART and evaluation of related adverse events are two essential aspects for optimal management of patients with HIV.

Purpose To monitor adherence to antiretroviral treatment and adverse events of the outpatients of an HIV referral centre (department of Clinical Infectious Diseases, Policlinico S.Orsola-Malpighi, Bologna).

Materials and Methods The pharmacist was introduced in the department of Clinical Infectious Diseases in order to distribute the antiretroviral drugs and give information on the proper storage, use and possible interactions associated with the treatment. The pharmacist gives out an adherence questionnaire (10 questions about adherence, co-administered drugs and adverse events) to each patient to complete and return during the following visit. This

information was entered into a database (Access) and the adherence to treatment and incidence of adverse events was calculated.

Results We analysed the adherence questionnaires of 659 patients, 74% of whom reported 100% adherence to treatment. Co-administered medicines may lead to poorer HAART adherence: patients taking polypharmacy showed medium-low adherence to treatment. Adherence was found to correlate inversely with the daily pill burden.

In terms of adverse effects, we developed a pharmacovigilance system, reporting 15 adverse drug reactions, 27% of which were rated severe. We analysed physical changes, gastrointestinal disorders and neuropsychiatric symptoms associated with the following regimens: efavirenz/emtricitabine/tenofovir, emtricitabine/tenofovir + atazanavir/ritonavir, efavirenz/emtricitabine/tenofovir, emtricitabine/tenofovir + atazanavir/ritonavir, emtricitabine/tenofovir + darunavir/ritonavir, abacavir/lamivudine + emtricitabine/tenofovir + darunavir/ritonavir, abacavir/lamivudine + atazanavir/ritonavir, abacavir/lamivudine + darunavir/ritonavir. Our results showed that the regimens with darunavir correlated with a lower incidence of side effects and perception of physical changes.

Conclusions The physician-pharmacist collaboration is an important support in monitoring adherence and adverse events related to HAART and contributes significantly to the optimal management of patients with HIV infection.

No conflict of interest.

DOI-047 MORPHINE, OXYCODONE AND FENTANYL PRESCRIBING PATTERNS IN THE LOCAL HEALTH AUTHORITY OF MESSINA, ITALY

doi:10.1136/ejhp-2013-000276.313

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Background Pain is associated with significant economic, social and health impact. The cost of uncontrolled pain is enormous, both to individuals and to society as it leads to a decline in quality of life and disability. Several publications and guidelines stress the efficacy and safety of opioid-based treatment for cancer and non-cancer pain management. Until recently Italian legislation was very restrictive concerning the use of opioids, making Italy one of the lowest users of medical opioids in Europe. In 2010 law no. 38 eased the prescription of opioids for cancer and non-cancer pain.

Purpose To evaluate the incidence and cost of using morphine (N02AA01), oxycodone (N02AA05) and fentanyl (N02AB03) in order to assess prescribing patterns in the Local Health Authority (LHA) between 01/01/2010 and 30/09/2012.

Materials and Methods Data were collected from 'Farmanalisi.it' database which records all prescriptions reimbursed by the Messina LHA. All consumption data were expressed in a standardised way and costs as direct costs to the LHA and recorded on a data sheet.

Results During the 2010–2011 period the consumption of morphine (os/IV) remained substantially stable (1,763 units in 2010 vs. 1,730 in 2011). By contrast, consumption of oxycodone and transdermal fentanyl rose (for oxycodone 3,742 units in 2010 vs. 3,888 in 2011; for transdermal fentanyl 13,680 units in 2010 vs. 13,881 in 2011). The same trend was recorded for the first nine months of 2012 with 1,600 units for morphine, 2,236 units for oxycodone and 7,499 for transdermal fentanyl. For the LHA, in the evaluated period, direct costs of transdermal fentanyl were higher (978,428.11€) than the value reported for oxycodone (180,042.89€) and morphine (46,279.96€).

Conclusions Data obtained confirm that, in the Messina LHA, many patients received transdermal fentanyl as a first option although it is recommended only when oral morphine is inadequate. This data could allow an evolution of strategies adopted to control

pain and form the basis for communication among healthcare providers, such as General Practitioners, in order to improve appropriate prescribing policies.

No conflict of interest.

DOI-048 NEW ORAL ANTICOAGULANTS: HOW ARE THEY BEING USED?

doi:10.1136/ejhp-2013-000276.314

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Background The expectations raised by the new oral anticoagulants (OACs) have led some experts to view them as the ideal substitute for anti-vitamin K.

Purpose To analyse the use of dabigatran and rivaroxaban in a Spanish tertiary hospital since their inclusion in the formulary to date.

Materials and Methods The period of study was January 2010–September 2012. We carried out a study on the patients prescribed either of the two new OACs included in the formulary. A data collection sheet was designed in which the parameters recorded were: gender, age, indication and observations (if any adverse reaction had been described).

Results In the period January 2010–September 2012, a total of 86 patients (38% male) were treated with rivaroxaban, with a mean age of 66 (21–91) years old; whereas in the period December 2011–September 2012 (dabigatran was included later in the formulary), 55 patients (60% male), with a mean age of 74 (45–93) years, were treated with dabigatran. 84 out of the 86 patients treated with rivaroxaban received it in prophylaxis after having undergone knee or hip replacement. Nevertheless, dabigatran was used mostly in non-surgery patients, only 2 out of the 55 patients were traumatology patients.

Only one minor bleed was reported in one patient diagnosed with atrial fibrillation and treated with dabigatran, and it should be taken into account that this patient exhibited thrombocytopenia at the time the bleeding occurred. No other adverse effects related to the administration of these drugs were found.

To date, the price of these new OACs is more than ten times higher than anti-vitamin K.

Conclusions Despite the fact that the new OACs have been shown as a good option compared to anti-vitamin K, their use in our hospital is still moderate, for two main reasons: their high cost and the uncertainty about their management in critical situations.

No conflict of interest.

DOI-049 OCTEOTRIDE IN GASTROINTESTINAL ANGIODYSPLASIA

doi:10.1136/ejhp-2013-000276.315

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Background Gastrointestinal angiodysplasia (GIAD) may either be asymptomatic or induce overt or occult bleeding with a high risk of recurrence. Numerous therapeutic options are available but an evidence base is lacking.

Purpose To analyse costs and improve the clinical parameters in patients with GIAD after intramuscular administration of long-acting octreotide (Oc-LAR) 10 mg/month.

Materials and Methods Retrospective observational study from January to December 2011. We reviewed the medical records of patients who were prescribed long-acting Octreotide for GIAD. Clinical data (haemoglobin, vials of iron needed, blood transfusions) and demographic characteristics of the patients were tabulated

using Excel. We compared clinical results pre- and post-Oc-LAR use. The χ^2 test was used for category variables, and the t-test was used for continuous variables with normal distribution using SPSS statistical software.

Clinical and monetary value were derived from publicly available data. The study perspective was from the hospital management point of view.

Results 17 patients were included in the study, 11 were men and 6 women. The mean age was 75.2 years. The direct costs were €350 per red blood cell transfusion, €167 per iron administration and €694.95 for Oc-LAR.

The mean Hb levels were 9.0 g/dl and 9.6 g/dl ($p < 0.0001$) before and after treatment. Blood transfusions decreased from 1.8 to 1.7 ($P = 0.258$). However iron requirements were higher after treatment started: 2.5 vials of iron, up from 1.9 ($P = 0.027$). And there was an increase in hospital admissions annually 3.3 vs. 2.3 before treatment ($P = 0.311$). So Oc-LAR use increased the average annual cost per patient by 8,401.6€ without stopping disease progression.

Conclusions Pharmacological treatments are typically considered in refractory cases of endoscopic failure and recurrent bleeding. Oc-LAR seems to be more suitable in terms of efficacy and tolerance according to the bibliography. However, our study shows that Octreotide long-acting formulation treatment was not cost effective and failed to stop the natural evolution of the disease.

No conflict of interest.

DOI-050 OFF-LABEL USES OF MYCOPHENOLATE MOFETIL

doi:10.1136/ejhp-2013-000276.316

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Background The implementing Law 1015/2009 normalises the compassionate use of investigational drugs, access to off-label and unauthorised drugs in Spain.

Mycophenolate mofetil/Mycophenolic Acid (MM/MA) have been used in off-label conditions to treat kidney diseases.^{1–5}

Purpose To describe the dose and effectiveness of MM/MA in the treatment of nephritis.

Materials and Methods Observational, cross-sectional study including all patients diagnosed with nephritis treated with MM/MA in off-label conditions during July 2012.

Diagnosis and dose were recorded. Serum creatinine and the value of urinary proteins were collected at the beginning of the treatment and during the month of the study.

Results 22 patients were included, 14 were treated with MA and 8 with MM.

Of the patients treated with MA, 50% asked to be treated for nephritis, 28.6% for lupus and 21.4% for polyarteritis nodosa. (Both the lupus and the polyarteritis nodosa were giving clinical kidney symptoms.)

The usual dosage was every 12 hours (12/14), the most used dose being 360 mg (10/14).

The mean serum creatinine at the beginning of treatment was 1.14 mg/dl (SD .4) and decreased to 0.95 mg/dl (SD 0.3) at the end of the study. The urinary proteins value decreased from 35.4 (SD 7.3) at the beginning of treatment to 26.2 (SD 3.2) at the end of the study.

Of the patients treated with MM 62.5% requested treatment of nephritis and 37.5% of lupus. (The usual dosage was every 12 hours (7/8), the most used dose being 500 mg (3/8), 400 mg (2/8), 1500 mg, 1000 mg and 250 mg (1/8).

The mean serum creatinine at the beginning of treatment was 1.35 mg/dl (SD 0.6) and decreased to 1.13 mg/dl (SD 0.5) at the end of the study. The urinary proteins value decreased from 30.11