Drug information

The effectiveness of mifamurtide in osteogenic sarcoma treatment cannot be considered as assessed due to the small sample size.

No conflict of interest.

DGI-035 EVALUATION OF THE SYSTEMIC TOXICITY OF DOXORUBICIN AFTER HEPATIC IODIZED OIL CHEMOEMBOLIZATION IN **HEPATOCELLULAR CARCINOMA PATIENTS**

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Background Chemoembolization of iodized oil into a hepatic tumour (hioCE) is a locoregional medical technique that consists of delivering selectively into tumour-feeding arteries, an anticancer drug emulsified in iodized oil followed by an occlusive agent (embolization agent). It enables higher intra-tumour drug concentrations to be obtained compared to intravenous treatment, with blood vessel occlusion causing local necrosis. hioCE using doxorubicin at 50 mg/m² is effective in the palliative treatment of hepatocellular carcinoma (HCC) with significant survival benefit compared with best supportive care. To our knowledge, no study has evaluated systemic doxorubicin toxicity after hioCE.

Purpose To evaluate systemic doxorubicin toxicity in HCC patients treated by hioCE.

Materials and Methods A 3-year retrospective study was performed in the Radiology and Pharmacy departments. Toxicity was assessed using WHO criteria. Data were collected from Chimio software and patient medical records. Mann Whitney and Chi2 tests

Results 94 HCC patients were treated with hioCE using doxorubicin. Median age was 64 years [28-89]. Toxicity occurred in 69 patients (73%). Main toxicities were digestive disorders (34 patients; 16 grade 3-4), cardiotoxicity (16 patients; 10 grade 3-4) and alopecia (13 patients; 8 grade 3-4). No statistical relationship was found between patient characteristics (age, sex, body mass index, medical and surgical history), HCC aetiology or characteristics, Child-Pugh score or hioCE practise and the occurrence or gravity of doxorubicin toxicity.

Conclusions More than half of the patients suffered doxorubicin toxicity after hioCE suggesting doxorubicin passed into the systemic circulation. Studies showed that the doxorubicin-iodized oil mixture was unstable. Although hioCE with doxorubicin is effective in HCC and doxorubicin toxicity occurring in our patients was

less severe than that of intravenous doxorubicin administration, doxorubicin tolerance after hioCE is debatable. The use of an anticancer drug that was more stable with iodized oil could decrease the passage of the drug into the systemic circulation. The use of doxorubicin-eluting beads for chemoembolization is much more expensive but could also be an alternative.

No conflict of interest.

DGI-036 EVOLUTION OF ANTIFUNGAL CONSUMPTION IN A GENERAL HOSPITAL

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Background Antifungal treatment is an important part of global expenditure. A significant increase in the use of these drugs does entail a higher cost.

It is hoped that the use of these drugs will continue to increase each year. It is important to know the drug use distribution through the different units and the monetary cost in order to put forward pharmacist interventions.

Purpose To describe the evolution of expenditure on, and consumption of, caspofungin, voriconazole, amphotericin B and fluconazole and significant fungaemia from 2009 to 2011.

Materials and Methods Observational, retrospective study, carried out in a General Hospital.

The consumption for every single patient of caspofungin, voriconazole, liposomal amphotericin B and fluconazole, from 2009 to 2011, were obtained from the Pharmacy Department Software databases (Langtools). Average prices were used to calculate the financial impact. In the microbiology department, blood cultures were done for every patient treated with these drugs for fungal iso-

Results Pharmaceutical spending on these four drugs versus general expenditure was 1.53%, 1.04% and 1.00% for the years 2009, 2010 and 2011 respectively. The evolution of consumption in units (including all presentations) and expenditure is shown in the following table (table 1).

The total consumption of the main services in the study period is shown in the following table (table 2).

The number of yeasts isolated from blood cultures was 20, 19 and 21 for the years 2009, 2010 and 2011 respectively, representing 2.48% of all positive blood cultures.

Abstract DGI-036 Table 1

	Units 2009	Spending 2009 (€)	Units 2010	Spending 2010 (€)	Units 2011	Spending 2011(€)
Caspofungin 50 mg vial	426	198,935.95	218	94,934.03	148	64.714,53
Voriconazole 200 mg vial	541	41,914.25	468	37,146.39	731	44.453,75
Liposomal Amphotericin B 50 mg vial	1456	142,091.04	1353	132,042.78	1792	174.885,93
Fluconazole 400 mg vial	2759	4,566.79	2701	4,799.73	2623	4.711,38
Total	5182	387,508.03	4740	268,922.93	5294	288,765.59
Total pharmaceutical expenditure		25,310,713		25,824,331		28,771,067

Abstract DGI-036 Table 2

	Units 2009	Spending 2009 (€)	Units 2010	Spending 2010 (€)	Units 2011	Spending 2011(€)
Caspofungin 50 mg vial	426	198,935.95	218	94,934.03	148	64,714.53
Voriconazole 200 mg vial	541	41,914.25	468	37,146.39	731	44,453,.75
Liposomal Amphotericin B 50 mg vial	1456	142,091.04	1353	132,042.78	1792	174,885.93
Fluconazole 400 mg vial	2759	4,566.79	2701	4,799.73	2623	4,711.38
Total	5182	387,508.03	4740	268,922.93	5294	288,765.59
Total pharmaceutical expenditure		25,310,713		25,824,331		28,771,067

Conclusions Antifungal spending is disproportionately high considering the low number of fungal isolates, and entails a high use of empirical and prophylactic treatment.

Haematology is, by far, the main department responsible for the use of antifungal treatment. Consumption of voriconazole and liposomal amphotericin B are increasing, meanwhile caspofungin is decreasing in recent years.

No conflict of interest.

DGI-037 FINGOLIMOD IN RELAPSING REMITTING MULTIPLE **SCLEROSIS: A CASE REPORT**

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Background Fingolimod has recently been authorised in our country (April 2011). It is the first orally administered diseasemodifying drug that has been approved for highly active relapsing remitting multiple sclerosis. So far, only one patient has been treated with it in our hospital, so we have limited experience in its use.

Purpose The case report relates to relapsing remitting multiple sclerosis (RRMS) patient with high disease activity under treatment with Fingolimod. We aim to describe the evolution of this patient during the treatment period.

Materials and Methods It was an observational, six-month prospective study.

The patient, a 32-year-old female, was diagnosed with RRMS in February 2004 after an episode of sensory deficits.

Results At first, she was treated with interferon b-1a, which was stopped in February 2006 and switched to mitoxantrone IV. The patient continued to have several relapses during the treatment with this immunosuppressant; one of these relapses required plasma exchange therapy. Her Expanded Disability Status Scale (EDSS) worsened to 6 points. Assuming a lack of efficacy, the patient started treatment with natalizumab in April 2007. During four years of treatment with natalizumab she showed remarkable clinical improvement and did not experience any new relapses. Her EDSS improved to 2.5. After this time and due to the high risk of developing progressive multifocal leukoencephalopathy (PML), she switched to fingolimod (December 2011).

Ten days after initiation, she developed a severe relapse that required hospital admission, high dose IV steroids and 3 cycles of plasma exchange therapy. Doctors concluded this relapse was in fact a rebound effect due to stopping natalizumab.

In February 2012 she restarted fingolimod; one month later she developed a new relapse, treated with high dose steroids.

In April and May 2012 she had two more relapses, with severe EDSS worsening and again managed with high dose steroids.

In May 2012, it was decided to stop treatment with fingolimod, and despite the risk of PML (JC virus +), natalizumab was restarted. Conclusions During six months of fingolimod treatment, the patient's condition further deteriorated (four relapses in six months), her EDSS worsened and showed a high disease activity. We conclude that the treatment was not effective in this patient.

No conflict of interest.

DGI-038 GEMTUZUMAB OZOGAMICIN AS SALVAGE TREATMENT IN **CHILDREN WITH ACUTE MYELOID LEUKAEMIA RELAPSE:** A RETROSPECTIVE STUDY

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¹A Giroud, ¹K Morand, ¹G Benoit, ²G Leverger. ¹Armand Trousseau Hospital, Pharmacy, Paris, France; ²Armand Trousseau Hospital, Pediatric oncology/haematology, Paris, France Background Gemtuzumab ozogamicin (GO) is a humanised anti-CD33 monoclonal antibody conjugated with calicheamicin. Several studies show its safety and efficacy in refractory/relapsed acute myeloid leukaemia (AML). Nevertheless in July 2010 it was withdrawn from the US market after a study failed to confirm the clinical benefits of GO.

Purpose Following this controversy, we conducted a retrospective study to evaluate its efficacy and safety in children with refractory/ relapsed AML.

Materials and Methods The study focused on the 19 children treated after approval by the French drug safety agency, between October 2006 and June 2012.

Results The median age at initial diagnosis was 6.7 years (0.5–15.3). Three patients were refractory to first-line treatment, one patient was in refractory first relapse, three were in first relapse after stem cell transplantation (SCT), three in second relapse after SCT, one in third relapse after SCT, seven were in first relapse and one in second relapse. Patients received: one dose of 3 mg/m² with cytarabine (day 1 to 7); or 9 mg/m² fractionated dose (on days 1, 4, 7) in monotherapy or associated with cytarabine (day 1 to 7); or 4.5 mg/m² on day 6 associated with fludarabine and daunorubicin liposomal. Nine complete remissions were obtained (48%) in 32 days, leading to further curative treatment. The one year overall survival was 26% (5 patients). For the others complete remission was maintained for 6–9 months before relapse or death. Grade 3–4 haematological adverse events were identified in all children including severe thrombocytopenia requiring transfusion. Sepsis (n = 2), fever (n = 3), vomiting (n = 6) were documented. One case of sinusoidal obstruction syndrome was reported.

Conclusions Children with refractory/relapsed AML have a dismal outcome and there is a lack of effective treatments. In our cohort GO led to nearly 50% of CRs and even if the long term survival is still unsatisfactory it should remain available in this indication.

No conflict of interest.

DGI-039 GUIDE TO THE PREPARATION AND ADMINISTRATION OF INJECTABLE CYTOTOXIC DRUGS

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Background The preparation of injectable cytotoxics is a key activity of many hospital pharmaceutical services. Due to the increasing availability of cytotoxic medicines, either branded or generic, the time spent by hospital pharmacists in search of information about reconstitution and/or dilution, storage and stability of these drugs has increased. In order to effectively respond to this need for information, it would be useful to have a database that holds all that information for all cytotoxic medicines currently available in Portugal.

Purpose To prepare a guide to the preparation and administration of all parenterally administered cytotoxics available in Portugal, which provides information on the reconstitution and/or dilution, storage and stability, routes of administration, infusion rate, as well as other relevant observations.

Materials and Methods Review of the summary of product characteristics (SPC) of all injectable cytotoxic drugs currently available in Portugal; consultation with the pharmaceutical manufacturers and analysis of the responses received.

Results A total of 153 injectable cytotoxic medicines were investigated (88 branded and 65 generic), comprising a total of 40 active substances. Of this total, 145 have marketing authorization in Portugal and 8 are used under special-use authorization. Significant variability in the information available about the reconstitution,