REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-278 EFFECTIVENESS AND SAFETY OF CISPLATIN PLUS GEMCITABINE IN METASTATIC BREAST CANCER

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10.1136/ejhp-2021-eahpconf.110

Background and importance Different studies in the literature have demonstrated promising efficacy of cisplatin–gemcitabine for the treatment of metastatic breast cancer. Real life studies are commonly performed to confirm the results.

Aim and objectives To analyse cisplatin–gemcitabine effectiveness and safety in patients with metastatic breast cancer.

Material and methods A retrospective observational study was conducted in a university hospital. Patients treated with cisplatin–gemcitabine from January 2007 to February 2020 were included. The following variables were recorded: age, hormone receptor (HR), human epidermal growth receptor-2 (HER2) status, duration of treatment, number of cycles, number and type of previous chemotherapy regimens, progression free survival (PFS) and overall survival (OS), calculated by the Kaplan–Meier method, and adverse events (AEs). Data were obtained from the electronic clinical records and the software where the chemotherapy treatments are registered.

Results 56 patients were included, with a median age of 56.5 years (range 30–82). 40 patients (71%) were HR positive, 13 patients (23%) were triple negative and 6 patients (11%) were HER2 positive. At the time of data analysis, one patient was still receiving treatment with cisplatin–gemcitabine and 55 had finished treatment, with a median duration of 2.8 months (4 cycles, range 1–10). Patients had a median of two previous chemotherapy lines in metastatic stage (range 0–4). 85.7% of patients received cisplatin–gemcitabine as metastatic therapy in the secondline or later. The most common regimens used before cisplatin–gemcitabine in metastatic disease were: non-pegylated–liposomal doxorubicin (54.2%), nab–paclitaxel (37.5%), paclitaxel–bevacizumab (35.4%), eribulin (27.1%), epirubicin–docetaxel (18.8%), paclitaxel monotherapy (16.7%), docetaxel monotherapy (14.6%) and pegylated–liposomal doxorubicin (12.5%), with other regimens used less frequently. Median PFS and OS were 3.4 and 6.8 months, respectively. 51.8% of patients had any AE during treatment and the most frequent were anaemia (62%), neutropenia (31%), thrombocytopenia (24%), peripheral neuropathy (17.2%) and asthenia (10.3%). Six patients interrupted their treatment due to AEs.

Conclusion and relevance Cisplatin–gemcitabine was shown to be another effective treatment option in metastatic breast cancer. However, several studies in the literature have shown better results for PFS and OS. This may be due to differences in the baseline characteristics of the patients and the use of previous chemotherapy regimens. Cisplatin–gemcitabine was well tolerated and in most cases the AEs did cause interruption of treatment.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-279 CANCER PAIN MANAGEMENT APPROACH CONSIDERING POTENTIAL DRUG INTERACTIONS IN PATIENTS RECEIVING ORAL ANTITUMOUR TREATMENT

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10.1136/ejhp-2021-eahpconf.111

Background and importance Cancer pain management is a recurrent topic in many oncology pharmacies. Drug to drug interactions with patients' current drugs, together with other parameters, is routinely assessed by pharmacists to obtain maximum efficacy with tolerable side effects.

Aim and objectives The aim was to evaluate drug-to-drug potential interactions with analgesics for mild to moderate pain in patients receiving oral cancer treatment.

Material and methods This was a retrospective observational study. All cancer patients treated with oral antineoplastic drugs at an oncology pharmacy unit were included in the analysis. The study period was from January to December 2019. Analgesics for mild pain (acetaminophen, NSAIDs) and mild to moderate pain (weak opioids) were included, according to ESMO Clinical Practice Guidelines for the management of cancer pain in adult patients (Fallon *et al*, 2018). For each patient, drug-to-drug interactions for 17 analgesics were evaluated using the Lexicomp database. Risk was rated as A (no interaction), B (no action needed), C (monitor therapy), D (modify regimen) or X (avoid combination).

Results 541 patients, receiving 46 different drugs for cancer treatment, were seen by an oncology pharmacist. All had their potential drug-to-drug interactions checked to assess available options for analgesia. Most patients (88%) had a potential clinically significant interaction between treatment and at least one of the analgesics studied.

78% of patients had at least one analgesic contraindicated due to potential interactions. In all of these patients, the contraindicated drug was metamizole (dipyrone), as it increases the myelosuppressive effect of the oncology drug. A few patients (0.9%) also had a weak opioid contraindicated as it enhances the depressive effect in the CNS. In 19% of patients, it was necessary to modify treatment, and in 20% an appropriate monitoring plan was recommended.

Conclusion and relevance Most cancer patients receiving anti-cancer oral drugs could have clinically relevant potential drug-to-drug interactions with drugs used for analgesia for mild and mild–moderate cancer pain. Oncology pharmacists should be aware of this and routinely check for potential interactions with anticancer treatment and analgesics, as part of their pharmaceutical care protocols, to define options for cancer pain control.

REFERENCES AND/OR ACKNOWLEDGEMENTS

None

Conflict of interest No conflict of interest

4CPS-280 BENEFITS OF PHARMACOKINETIC ESTIMATION OF METHOTREXATE LEVELS IN PAEDIATRIC OSTEOSARCOMA PATIENTS

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10.1136/ejhp-2021-eahpconf.112

Background and importance Monitoring of methotrexate serum levels in osteosarcoma paediatric patients includes estimation of serum levels of methotrexate 24 hours after initiation of the infusion ([MTX_{24h}]), which allows folinic acid rescue to be started at adjusted doses. When pharmacokinetic estimation is not possible, the standard rescue (15 mg/m²/6 hours) is recommended and subsequently adjusted according to the real [MTX_{24h}].

Aim and objectives To evaluate the correlation and concordance of the estimated and real [MTX_{24h}], and the benefits of the estimation in comparison with the dosage by protocol.

Material and methods A retrospective study of paediatric patients treated with 12 g/m² methotrexate monitored by the pharmacy department from January 2014 to June 2020 was conducted. Estimated [MTX_{24h}] was determined with a Bayesian model with PKS software.

Variables collected were age, sex, number of cycles received, estimated and real [MTX_{24h}] and folinic rescue dose. Pearson and intraclass correlation coefficients between real and estimated [MTX_{24h}] were calculated. The agreement between the dosage of folinic acid by protocol and by estimating [MTX_{24h}] was assessed with the Cohen kappa coefficient.

Results 23 patients, 56.5% (13) men, median age 14 (4–17) years, received 152 cycles of methotrexate. The median number of cycles per patients was 8 (2–8). Median estimated [MTX_{24h}] was 7 (2–80) and real [MTX_{24h}] was 8 (1–85). The Pearson's correlation coefficient and intraclass correlation coefficient for real and estimated [MTX_{24h}] were $r=0.949$ and $CCI=0.974$, respectively, indicating a high linear correlation and concordance between the two.

In 71.8% (94) of the cycles, the estimated folinic rescue matched with the dose which the patient should receive according to real [MTX_{24h}]. Assuming the dosing of folinic acid at 24 hours by protocol (15 mg/m²/6 hours) in all cases, only 35.1% (46) of patients would have received the correct dose. The Cohen kappa between the two methods was 0.189, indicating only slight agreement between both methods in favour of estimating [MTX_{24h}].

Conclusion and relevance Estimated and real [MTX_{24h}] showed high correlation and concordance, and in most cases the folinic acid rescue dose was correctly administered based on the estimated [MTX_{24h}]. These results seem to indicate that the estimation of [MTX_{24h}] and posterior estimation of folinic acid rescue are superior to systematic administration of 15 mg/m²/6 hours.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-281

HIGH DOSE METHOTREXATE IN PAEDIATRIC OSTEOSARCOMA PATIENTS: EFFECTIVENESS AND SAFETY

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10.1136/ejhp-2021-eahpconf.113

Background and importance Osteosarcoma is the most frequent bone tumour, and is more prevalent in paediatric patients. Treatment of osteosarcoma in paediatric patients includes administration of methotrexate at high doses, which allows the drug to penetrate the bone tissue in adequate concentrations. Serum peak methotrexate levels between 1000 and 1500 µM have been correlated with efficacy.

Aim and objectives The objective of this study was to evaluate the effectiveness and safety of methotrexate 12 g/m² as treatment for osteosarcoma in paediatric patients.

Material and methods This was an observational retrospective study including paediatric osteosarcoma patients treated with 12 g/m² methotrexate infusion from January 2014 to June 2020. Data were extracted from the patients' clinical history. Peak methotrexate serum levels were extracted immediately after the 4 hour infusion. Variables collected were: age, sex, number of cycles received, peak methotrexate serum levels and adverse events associated with the methotrexate infusion during hospitalisation.

Results 25 patients, 56% (14) males, median age 14 (4–17) years, received 159 cycles of methotrexate. The median number of cycles per patient was 8 (2–8). Median peak methotrexate serum levels were 1280 (280–2980) µM; 74.84% of peak serum levels were >1000 µM.

Conclusion and relevance When comparing our results with published studies, we found that the patients included in our study achieved effective concentrations of methotrexate at a higher percentage (75% vs 63%)¹ with severe adverse events being less frequent (9% vs 39%)². According to these results, methotrexate infusion was effective and safe in the studied population.

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Conflict of interest No conflict of interest

Abstract 4CPS-281 Table 1 Adverse events associated with methotrexate per cycle

Adverse event						
Grade	Nausea	Mucositis	Diarrhoea	Cutaneous	Respiratory	Other
I	19	3	5	1	1	4
II	68	0	2	1	0	3
III	10	0	0	0	0	1
IV	0	0	0	0	0	0

96% (24) of patients presented with at least one adverse event during methotrexate infusions. Few adverse events apart from nausea were described. Only 9.33% (11) of adverse events were classified as severe.