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%), etoposide–docetaxel (18.8%), paclitaxel–docetaxel (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 None

Conflict of interest None
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 ([MTX24h]), 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 [MTX24h].

Aim and objectives To evaluate the correlation and concordance of the estimated and real [MTX24h], 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 [MTX24h] was determined with a Bayesian model with PKS software.

Variables collected were age, sex, number of cycles received, estimated and real [MTX24h] and folinic rescue dose. Pearson and intraclass correlation coefficients between real and estimated [MTX24h] were calculated. The agreement between the dosage of folinic acid by protocol and by estimating [MTX24h] 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 patient was 8 (2–8). Median estimated [MTX24h] was 7 (2–80) and real [MTX24h] was 8 (1–85). The Pearson’s correlation coefficient and intraclass correlation coefficient for real and estimated [MTX24h] 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 [MTX24h]. 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 [MTX24h].

Conclusion and relevance Estimated and real [MTX24h] showed high correlation and concordance, and in most cases the folinic acid rescue dose was correctly administered based on the estimated [MTX24h]. These results seem to indicate that the estimation of [MTX24h] 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

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

<table>
<thead>
<tr>
<th>Grade</th>
<th>Nausea</th>
<th>Mucositis</th>
<th>Diarrhoea</th>
<th>Cutaneous</th>
<th>Respiratory</th>
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</tr>
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</table>

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.