had to reduce the dose, of whom 28.57% had to reduce to the minimum dose of 75 mg while the rest remained on the 125 mg dose. The main cause of dose reduction for both was neutropenia (50% for ribociclib and 72.22% for palbociclib). The next cause was liver toxicity (37.55%) from ribociclib and gastrointestinal upset (16.67%) from palbociclib.

Conclusion and relevance Comparing effectiveness, a greater PFS was found for ribociclib compared with palbociclib (2.09 months); there was a higher percentage of patients with progression after treatment with palbociclib (45.83% vs 16.67%). Regarding toxicity, ribociclib had a higher toxicity profile than palbociclib. Both required dose adjustment, greater for palbociclib, the main cause in both being neutropenia.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

Background and importance Methotrexate (MTX) is widely used in paediatric chemotherapy treatment and is effective. However, it presents with significant toxicity. Myelopathy is a rare but serious complication, usually related to mechanical damage caused by multiple lumbar punctures and the administration of drugs by this route. The main symptoms are loss of sensitivity, alteration of motor neurons, root pain and sphincter incontinence.

Aim and objectives We present a clinical case of a Caucasian girl with precursor B cell lymphoblastic lymphoma, stage IV, that affected the CNS type 3. She presented with neurotoxicity after administration of intrathecal MTX. She received treatment under the EURO-LB02 protocol.

Material and methods After seven doses of intrathecal triple treatment the patient continued from TIT and intravenous MTX was gradually titrated to full doses. Currently, the patient is in the reinduction phase and has shown partial recovery from myelitis. She was rescued with leucovorin after intravenous MTX and levels of MTX were always within the normal range without notable toxicity.

Conclusion and relevance MTX may cause spinal cord dysfunction in children, especially when the intrathecal route is used. SNPs in enzymes involved in pharmacokinetics and pharmacodynamics may be the cause. However, more studies are needed to confirm these findings and translate them into information applicable to clinical practice.
REAL SAFETY OF DARATUMUMAB IN MYELOMA MULTIPLE
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Background and importance The overall survival of patients with multiple myeloma (MM) has changed dramatically in the last decade. Immunotherapy has emerged as a promising treatment, such as daratumumab. This human monoclonal IgG kappa antibody that targets CD38 is used in monotherapy or in combination, and has demonstrated durable responses. But good clinical management of toxicities is needed to reach the goal of therapy.

Aim and objectives To assess the safety of daratumumab in monotherapy and in combination with other agents used in our institution, and to review the clinical management of toxicities.

Material and methods A retrospective observational study was conducted in a second level hospital. We reviewed the medical records of all patients diagnosed with MM who received at least one cycle of daratumumab as monotherapy or as combination therapy in our hospital until August 2020. Collected data were: sex, age, cytogenetic risk, prior line of therapy, prior autologous stem cell transplantation (ASCT), daratumumab monotherapy or combination therapy, adverse drug reactions (ADRs), grade and clinical management (supportive treatments, temporary interruptions and permanent discontinuations).

Results 33 patients received at least one cycle of daratumumab and were included (26% men). Median age was 64 (42–77) years, 26% (8) had high cytogenetic risk abnormalities, median number of prior lines of therapy was 2 (0–6) and 74% (23) of patients received daratumumab in combination therapy. Average number of cycles received was 8 (1–38). 39% (13) of patients had infusion reactions (IRs) but the majority (92%) occurred during the first infusion and were grades 1–2. We registered 22 haematological severe ADRs (grades 3–4) and the most common was thrombocytopenia (60%), followed by neutropenia (22%), all requiring supportive treatment, and in 32% temporary interruption of treatment was necessary. 28 non-haematological severe ADRs (grades 3–4) were registered, 50% were severe infections, most of them respiratory that required temporary interruption to therapy, and 10 (71%) needed hospital admission. Almost one in three patients experienced permanent discontinuation of daratumumab related to toxicity (90% receiving combination therapy).

Conclusion and relevance Most adverse reactions related to daratumumab therapy were clinically manageable, but the incidence of severe haematological toxicity and severe respiratory infections makes close monitoring of side effects necessary, along with practical management strategies to reach the maximal benefit.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

INCIDENCE AND MANAGEMENT OF ETOPOSIDE HYPERSENSITIVITY IN PAEDIATRIC PATIENTS
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Background and importance Etoposide is widely used in paediatric chemotherapy treatment, although hypersensitivity can be severe and treatment limiting. There are conflicting data in the literature regarding the incidence of etoposide hypersensitivity reactions in adults and children. Reported rates of hypersensitivity range from 2% to 51%.

Aim and objectives The aim of this study was to assess the incidence of etoposide hypersensitivity and to evaluate potential risk factors for hypersensitivity in paediatric patients in a third level hospital.

Material and methods A retrospective observational study was conducted in paediatric patients treated with etoposide from June 2013 to September 2020. Data collected were: demographics (age, sex), diagnosis, dose, infusion rate, infusion concentration, symptoms of hypersensitivity, CTCAE grade of hypersensitivity reaction and management of hypersensitivity reaction. Data were collected from the electronic medical records and pharmacy records.

Results 213 patients were treated with etoposide during the period of the study. Mean age was 6.75 (range 0.16–17) years and 58.68% were male. Indications for etoposide were lymphocytic acute leukaemia 20.18%; neuroblastoma 16.9%; Ewing’s sarcoma 16.9%; Hodgkin’s lymphoma 11.27%; myeloid acute leukaemia 8.9%; and other 25.82%. Doses administered ranged from 200 to 100 mg/m² and from 2.5 to 6 mg/kg. Median infusion rate was 55 (2–200) mg/hour. Median infusion concentration was 0.3 (0.2–0.5) mg/mL. Hypersensitivity reactions occurred in 23 (10.8%) patients; 3 and 20 cases were classified as grade I and grade II of the CTCAE, respectively. Symptoms of hypersensitivity were lip cyanosis (n=7), pruritus (n=7), flushing (n=7), nausea (n=5), cutaneous rash (n=5), cough (n=4), rhinoconjunctivitis (n=1), hypotension (n=1), shortness of breath (n=1), abdominal pain (n=1), facial parasthesia (n=1), fever (n=1) and angioedema (n=1). All hypersensitivity reactions were successfully managed with medication (corticoids and antihistamines). Subsequent doses were administered with premedication and reduction of the infusion rate. We did not observe any statistically significant associations between the variables collected and the appearance of hypersensitivity reactions.

Conclusion and relevance The incidence of hypersensitivity reactions was moderate, affecting approximately 10% of patients. All hypersensitivity reactions were mild and were resolved by standard treatment. We were unable to establish if any of the variables collected were risk factors for hypersensitivity reactions, probably due to the small sample size derived from the rarity of the event. Other studies have observed a relationship between the rate of infusion and the concentration of etoposide.