

programme for outpatient and medical records was consulted. Data collected for each patient were: sex, age, menopause status, performance status (PS), cancer stage, presence of visceral metastatic disease, therapeutic scheme and number of cycles received. The safety profile was assessed from the number of adverse events (AE), and the severity of AEs was graded on the basis of the common terminology criteria for adverse events, V.5.0. Number of patients and reasons for delays and dose reductions were also determined.

Results 34 patients, 100% women, were included, with an average age of 60 (47–81) years, of whom 71% were postmenopausal. 29 patients presented at the beginning of treatment with PS \leq 1. The percentage of patients with metastatic disease was 100%, of whom 76% had visceral metastases. The schemes, average numbers and range of cycles were: palbociclib 125 mg every 3 weeks, 7 (1–17) cycles. 105 AE occurred in 31 patients (91%): 54 haematological, 23 metabolic, 10 digestive, 7 asthenia, 2 cases of infections and 9 other causes. The degree of severity was: anaemia, anorexia asthenia, diarrhoea, dysgeusia, increased levels of GGT/AST/ALT/LDH, mucositis, nausea, neutropenia, itching, palmar–plantar erythrodysesthesia syndrome, thrombopenia, urticaria and vomiting, grade 1 (59%); anaemia, anorexia, asthenia, headaches, GGT increased, infections, mucositis, nausea, neutropenia and vomiting, grade 2 (30%); and asthenia, neutropenia and GGT increased, grade 3 (12%). There were 13 patients who delayed treatment, and neutropenia was the reason in 85% of patients. 6% of patients had reduced doses of palbociclib because of neutropenia or mucositis.

Conclusion and relevance There was a high incidence of AE, the most frequent being grade 1. The most common AE were haematological, with neutropenia being the highest degree. Our studies suggested a high percentage of delays and dose reductions.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

5PSQ-160 MOGAMULIZUMAB EXPERIENCE IN ADVANCED SEZARY SYNDROME: A CASE REPORT

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Background and importance Sezary syndrome (SS) is a primary cutaneous T cell lymphoma characterised by erythroderma, lymphadenopathy and leukaemic involvement of the peripheral blood. The high relapse rates and poor prognosis complicate its clinical course and treatment. Mogamulizumab is an anti-CC chemokine receptor 4 monoclonal antibody that has been recently approved for the treatment of adult patients with relapsed or refractory mycosis fungoides or SS who have been treated with at least one prior line of therapy.

Aim and objectives To describe the use of mogamulizumab in a patient with SS as well as the safety of this new treatment.

Material and methods We ran a descriptive study of SS in a 77-year-old woman with erythema for 8 years. Skin lesions were widely distributed over 80% of her body. The patient was initially diagnosed with contact dermatitis and then psoriasis. She received various treatments without success:

antihistamines, topical corticosteroids, acitretin, cyclosporine, oral prednisone, phototherapy, ustekinumab, ixekizumab, methotrexate and bexarotene. In June 2020, due to new recurrences, additional skin biopsy and study of bone marrow were done to determine the specific type of skin lesions. Stage IV SS (pT4pM0pN0 B2) was diagnosed, and physicians decided to start expanded access treatment with mogamulizumab.

Results The patient received eight doses (80 mg/dose) of mogamulizumab from June to October 2020. It was administered with the approved protocol: 1 mg/kg dose, as an intravenous infusion over at least 60 minutes, on days 1, 8, 15, and 22 of the first 28 day cycle, then on days 1 and 15 of each subsequent 28 day cycle until disease progression or unacceptable toxicity. The woman presented good clinical evolution with reduction of skin lesions and symptoms. The treatment was well tolerated, with few reported adverse side effects: low grade fever after the first infusion and grade IV afebrile neutropenia after the sixth dose. Severe neutropenia was successfully treated with granulocyte colony stimulating factors and the patient was able to continue treatment.

Conclusion and relevance Mogamulizumab was used successfully to date in our case. Although more and longer treatment periods are needed, mogamulizumab seems to be a well tolerated treatment option for SS.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

5PSQ-161 EFFECTIVENESS AND SAFETY OF PALBOCICLIB AND RIBOCICLIB

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Background and importance Several trials have demonstrated the benefit of anti-CDK4/6 inhibitors plus endocrine therapy in oestrogen receptor positive (ER+) advanced breast cancer (aBC), in first or subsequent lines of therapy. Based on clinical trials, palbociclib and ribociclib are equally effective in either firstline or secondline therapy for advanced ER+ aBC, however, different toxicity profiles have been reported.

Aim and objectives To assess progression free survival (PFS) and safety of palbociclib and ribociclib in real clinical practice.

Material and methods An observational, retrospective, descriptive study was conducted in patients with aBC treated with palbociclib and ribociclib between February 2018 and September 2020. Age, doses, adverse events, time to progression or death, and medical history were collected.

Results 42 patients were included (24 received palbociclib and 18 received ribociclib). Ribociclib: mean age at the start of treatment was 58.94 ± 11.79 years. 16.67% of patients withdrew their treatment due to toxicity. 16.67% progressed (PFS of 9.9 ± 5.07 months). Patients began with doses of 600 mg: almost 40% of patients had to reduce the dose, of whom 28.57% had to reduce it to the minimum dose of 200 mg and the rest maintained on the 400 mg dose.

Palbociclib mean age at the start of treatment was 59.37 ± 10.74 years. There were only two cases of toxicity (8.33%). 45.83% of patients progressed (PFS of 7.81 ± 6.26 months). Patients started with a dose of 125 mg: 58.33% of patients

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

5PSQ-162 METHOTREXATE INDUCED MYELITIS IN A CAUCASIAN GIRL WITH LYMPHOBLASTIC LYMPHOMA AND PHARMACOGENETIC STUDY: A CASE REPORT

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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 (TIT) the patient began to experience distal tremor with numbness in the feet and slight ataxia. Gradually, the numbness increased and she developed areflexic paraparesis with static and kinetic ataxia that prevented her from walking. There was no cognitive impairment. MRI showed areas of leucoencephalopathy and homogeneous hyperintensity in the posterior segment from T1 to T12, suggesting dorsal myelitis. Folic acid and vitamin B12 levels were normal. Lymphoblastic invasion of the CNS was eradicated. To treat myelitis, she received methylprednisolone, dextromethorphan, s-adenosylmethionine, folinate, cyanocobalamin and intensive rehabilitation. Due to the patient's condition, we analysed 22 single nucleotide polymorphisms (SNPs) associated with the MTX metabolic pathway by TaqMan real time PCR.

Results 10 altered SNPs were found, mainly in genes encoding transport proteins (ABCB1 and ABCG2) and enzymes in the folate pathway (MTHFR) that could explain the toxicity manifested. However, there was low level evidence to support it. During subsequent cycles of chemotherapy, MTX was discontinued 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.

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5PSQ-163 INCIDENCE OF NEUTROPENIA AND EFFECTIVENESS OF PALBOCICLIB IN CLINICAL PRACTICE IN METASTATIC BREAST CANCER AFTER 4 YEARS OF USE

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Background and importance The inhibitor of cyclin dependent kinases 4 and 6, palbociclib, was a major advance in the treatment of metastatic breast cancer.

Aim and objectives To describe the effectiveness and incidence of neutropenia with palbociclib in clinical practice.

Material and methods A retrospective study was conducted in patients with metastatic or locally advanced breast cancer treated with palbociclib on any line in a tertiary hospital between July 2016 and August 2020. Demographic variables were collected: start and end date of the drug, concomitant hormonal treatment and treatment with denosumab. The presence of neutropenia was assessed before the start, on day 15 of the first cycle and with each reduction.

Results 58 patients were included with a median age at the start of palbociclib treatment of 59.0 years (33–87); the median cycle was 9 (2–34). 50% were on concomitant treatment with fulvestrant, 43.1% with letrozole, 3.4% with goserelin, 1.7% with anastrozole and 1.7% with exemestane. 44.8% of patients were treated with denosumab for bone metastases. The average neutrophil count was reduced by 52.9% from the beginning to the middle of the first cycle, with neutropenia appearing in 69.0% of patients (1.7% grade 4; 22.4% grade 3; 24.2% grade 2, 20.7% grade 1). 44.8% (26) had a first level reduction to 100 mg, with neutropenia appearing in 92.3% of these (15.4% grade 4; 61.5% grade 3; 15.4% grade 2). 46.2% of the previous patients (12) required a further reduction to 75 mg, with neutropenia appearing in 91.6% (58.3% grade 3; 25% grade 2; 8.3% grade 1). The average progression free survival was 17.6 (±1.8) months. Overall survival averaged 25.7 (±1.3) months. Patients with dose reductions were not more likely to progress (p=0.196). 51.7% received palbociclib as firstline, 32.8% as secondline and 15.5% as successive lines of treatment.

Conclusion and relevance Haematological toxicity in the form of neutropenia was frequent, from the first cycle, and remained despite successive dose reductions; reductions were needed in almost half of the patients. However, these dose