maintained MMR $\geq$ 4.5 log for at least 36 months prior to treatment interruption. These patients were candidates for discontinuation of ITK. Molecular monitoring of bcr-abl oncogene levels was performed using the real time reverse polymerase chain technique with the GeneXpert automated system with a sensitivity of 5 log.

Results Thirty patients with CP-CML were discontinued: 13 discontinued imatinib treatment, 3 discontinued dasatinib treatment and 14 discontinued nilotinib treatment. The preliminary rates of molecular relapse free survival and treatment free remission were consistent with those obtained in clinical trials, and no progression to advanced stages of the disease was reported. With a median follow-up of 15 months, 78% remained without specific treatment with ITK and had not lost MMR. Relapse occurred before 6 months of discontinued treatment with a median of 4 months. Four patients lost MMR, recovering all MMR 4.5 and 5.0 at 3 months after restarting ITK treatment.

Conclusion and relevance The results contribute towards reassurance of the safety of TKI treatment discontinuation in real life clinical practice, under close molecular monitoring. Resolution of TKI related toxicity might translate to clinical benefit for patients with CP-CML with a potential improvement in quality of life.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-081 GEFITINIB IN NON-SMALL CELL LUNG CANCER: EFFECTIVENESS AND SAFETY

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Background and importance Epidermal growth factor receptor (EGFR) tyrosine kinase inhibitors (TKIs) are the preferred firstline treatment for non-small cell lung cancer (NSCLC) in patients with an activating EGFR mutation. TKIs have consistently shown a greater response, longer progression free survival (PFS) and improved quality of life compared with chemotherapy in patients who have a driver mutation in the EGFR gene.

Aim and objectives To analyse the survival impact of gefitinib on patients with lung adenocarcinoma with the activating tyrosine kinase mutation of the EGFR (EGFR-TK) and to study its safety.

Material and methods This was an observational retrospective study carried out between July 2015 and March 2018. All patients with NSCLC undergoing treatment with gefitinib were included. Patient data were taken from clinical records. Variables analysed were demographics (age and sex), clinical variables (diagnosis, stage, line of treatment, dose administered and performance status (PS) according to the ECOG scale) and other variables (smoking). Efficacy end point was progression free survival (PFS) assessed by RECIST 1.1 criteria. Adverse reactions and comorbidities were also assessed. Analysis of PFS was performed using the Kaplan–Meier curve (SPSS V.17).

Results Thirty-one patients were included with activating EGFR mutations: 74.2% were women, average age was 69.5 ±11.4 years, 64.28% had ECOG-PS 0–1 and 28.57% were current or past smokers. NSCLC stage was IV in 100% of patients. Regarding comorbidities, 58.1% suffered from high blood pressure, 25.8% from diabetes, 16.1% from coronary heart disease, 29% from asthma/chronic obstructive pulmonary disease and 3.2% from chronic kidney disease.

Patients started therapy with gefitinib as firstline therapy in 58.1% of cases, 12.9% as secondline and 29% as thirdline. One patient stopped his treatment after 1 week due to diarrhoea. Median PFS was 7 months (95% CI 3–12). Adverse reactions included digestive toxicity: 22.57% of patients developed grade 1 (G1) diarrhoea and 14.28% G1 cutaneous toxicity. Other toxicities were conjunctivitis in 3.57% of cases. None of these was related to the comorbidities that patients presented at diagnosis.

Conclusion and relevance Gefitinib showed similar efficacy to the Interest phase III study (n=44) and slightly lower efficacy than the Ipass (n=261) and Isel (n=189) phase III studies (PFS 9.5–10.8). Further analysis in real world situations is necessary to accurately assess PFS. In general, gefitinib was well tolerated.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-082 RISK OF MYELOTOXICITY IN NON-CANCER PATIENTS TREATED WITH CHEMOTHERAPY

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Background and importance Myelotoxicity is a main concern when treating cancer patients with chemotherapy. It compromises safety but also the dose intensity received by the patient and thus treatment prognosis. One study (Katsifis, 2002) showed that the incidence of myelotoxicity and its clinical consequences was very low in patients with systemic lupus erythematosus (SLE) receiving cyclophosphamide. To our knowledge, this has not been studied in other non-tumour diseases.

Aim and objectives We aimed to assess the risk of developing clinically important myelotoxicity in non-cancer patients receiving intravenous cyclophosphamide.

Material and methods A retrospective study was carried out from January 2001 to July 2019. All patients who had received intravenous cyclophosphamide to treat a non-tumour disease where included. Blood analysis test results up to a month after completing treatment were collected. Myelotoxicity was categorised according to the common terminology criteria (CTC) for adverse events, V.5.0. Grade $\geq$2 neutropenia and thrombocytopenia were considered clinically relevant.

Results Forty-eight patients (56% women) and 277 cycles were analysed. Median age at initiation of therapy was 48.1 (IQR 38) years. One in three patients (35%) had diseases other than SLE. Most patients (72.9%) had no impaired neutrophil or platelet counts. For those who had, they were considered severe (grade 3) or life threatening (grade 4) in 7 and 2 patients, respectively.

Neutropenia (all grades CTC) occurred after 24 administrations (8.6%) and was grade ≥2 in 8 courses (2.9%), and grades 3 and 4 in 5 and 3 courses, respectively. Thrombocytopenia grade ≥2 occurred in 10 courses (3.6%), and was grade 3 in 3 cycles, No patient developed grade 4 thrombocytopenia.

No statically significant relationship was found between age and primary diagnoses.

Conclusion and relevance Although the incidence was low, severe and life threatening myelotoxicity was a serious side effect in non-cancer patients receiving cyclophosphamide and should be closely monitored.

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No conflict of interest.

4CPS-083 SAFETY AND TOLERABILITY OF PALBOCICLIB IN CLINICAL PRACTICE IN A TERTIARY HOSPITAL

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Background and importance Due to its recent commercialisation, the safety profile of palbociclib is undergoing special surveillance. Tolerability and safety problems often lead to dose reductions, introduction of supportive treatment or even treatment discontinuation.

Aim and objectives To evaluate the safety and tolerability of palbociclib in clinical practice in a third level hospital.

Material and methods This was retrospective cohort study. Inclusion criteria were all patients who started treatment with palbociclib between 1 January 2019 and 31 August 2019. Toxicity level was classified according to CTCAE V.5.0. Demographic and clinical data were collected from the patient electronic medical records.

Results Forty patients were included (n=40), all women, with a median age of 60 years (range 34–88). All had an ECOG performance status of 0–1 at the time of initiation of palbociclib. Ten patients received palbociclib in combination with fulvestrant and 30 in combination with an aromatase inhibitor. The median number of cycles received was 4 (1–8).

Haematological toxicities detected were grade 1–2 neutropenia (30% of patients), grade 3–4 neutropenia (47%), thrombocytopenia (37%), anaemia (45%), lymphopenia (7%) and leucopenia (35%). No patient suffered from febrile neutropenia. The incidence of infections during treatment was 5%. Other non-haematological adverse events detected with an incidence >5% included asthenia (15%), nausea (15%) and hypertransaminasaemia (7%).

Toxicity led to delay or temporary interruption of treatment in 50% of patients (median 1 interruptions/delays of treatment, range 1–3). Dose reduction to 100 mg was required in 22.5% of patients. No patient required a second reduction in dose. Three patients (7.5%) required administration of G-CSF as supportive therapy. Only one patient had to stop treatment permanently due to toxicity.

Conclusion and relevance Our population showed mainly haematological toxicities, with an incidence of neutropenia similar to clinical trials. However, the incidence of infections and non-haematological toxicities was generally lower than reported in clinical trials, probably due to the short revision period. Treatment was generally well tolerated in most patients, and adverse events were easily controlled, preventing patients from discontinuing treatment permanently. Further research will be needed to determine whether delays/temporary interruptions of treatment and dose reductions might affect its efficacy in the long term.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-084 ANTHRACYCLINE DOSAGE IN PAEDIATRIC OBESE PATIENTS

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Background and importance In 2016, the World Health Organization estimated that 41 million children aged <5 years were overweight. Clinicians are increasingly likely to have obese children requiring chemotherapy under their care. Optimal drug dosing for this population is unclear. Anthracyclines are often used in paediatric cancers and given its cardiotoxicity, optimising the dose is mandatory.

Aim and objectives To clarify the most adequate anthracycline dose in obese children with the available safety, effectiveness, pharmacokinetic and pharmacodynamic data.

Material and methods A systematic review was carried out in PubMed, Scopus and Web of Science in March 2019 with 'obese OR obesity' in the title and the name of each drug (daunorubicin/doxorubicin/epirubicin/idarubicin) in the topic or equivalent. Articles with a reference to the paediatric population in the title were included. Those that did not provide relevant information for the purpose of our study, written in a language other than English/Spanish and which did not allow conclusions to be made were excluded. Articles that used a different obesity criterion were selected when providing data of interest. Article references were reviewed to identify additional studies.

Results Fourteen articles were found. Ten were excluded because no dosage information was given or because of duplications. Four articles were analysed: three for doxorubicin and one for daunorubicin. The efficacy of doxorubicin was measured in one article in which the patient achieved complete remission using adjusted doses. No changes in the ECG were found during treatment or at 2 months or 2 years after treatment ended. No other specific toxicity was observed. The pharmacokinetics of doxorubicin are controversial. One article found no difference in clearance using adjusted weight versus actual weight; the other showed lower clearance in obese paediatric patients than in normal weight paediatric patients ($p<0.05$).

For daunorubicin and doxorubicin, pharmacokinetic in vitro models suggested that the presence of adipocytes markedly reduced the clearance of chemotherapy agents used as induction therapy in ALL.