Results 30 patients were treated with tofacitinib from 2017 to March 2020, 23 women and 7 men, with a median age of 55 (48–62) years; 40% of patients were overweight. 23 patients were diagnosed with rheumatoid arthritis, 3 patients with psoriasis arthritis, 1 patient with vitiligo, 1 patient with alopecia areata and 1 patient with polyarthritis. 50% of patients were pre-exposed to at least one biological agent and all of the patients were pre-exposed to methotrexate, leflunomide and/or hydroxychloroquine. Median time to stop tofacitinib was 307 (114–557) days. Reasons for stopping tofacitinib were: insufficient response (n=9), infection (n=1), headache (n=3), haematemesis (n=1) and pregnancy (n=1). 15 patients have continued treatment with tofacitinib with a good response. Elevation of liver enzymes, or changes in the levels of lymphocytes, neutrophils and haemoglobin have not been detected in any patient. 30% of patients had adverse events; more frequent adverse events were infections in 13% of patients and headache in 13% of patients.

Conclusion and relevance The efficacy and safety of tofacitinib have been demonstrated in clinical trials. This retrospective analysis of real life data showed that tofacitinib was also effective and safe in a real life setting but only 50% of the patient cohort achieved a response with a dose of tofacitinib 5 mg twice daily. Due to the size of the group, these results should be interpreted with caution; future analysis in clinical practice is necessary.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-311 REAL WORLD TOXICITY AND MANAGEMENT OF CHIMERIC ANTIGEN RECEPTOR T CELL THERAPIES TARGETING CD19 IN PATIENTS WITH HAEMATOLOGICAL MALIGNANCIES

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Background and importance Chimeric antigen receptor-T (CAR-T) has demonstrated clinical efficacy in haematologic malignancies but it also has a relevant toxic side effect profile.

Aim and objectives To describe the toxicity and management of CAR-T cell therapies (CARTs) (tisagenlecleucel (Tisa-cel) and axicabtagene ciloleucel (Axi-cel)) in a real world population with haematological malignancies.

Material and methods A retrospective study was conducted in all patients treated with CARTs in our hospital (August 2019 to September 2020). Data collected included age, gender, diagnosis, hospital stay, admission to the intensive care unit (ICU), length of ICU stay and the main adverse events (AE) detected (cytokine release syndrome (CRS), neurological toxicity, hypogammaglobulinaemia, febrile neutropenia and infections) and need for tocilizumab and/or corticosteroids to treat AE. Statistical analysis was performed using SPSS V.21.0.

Results 32 patients were included (53.1% men). Axi-cel was administered to 53.1% of patients, of whom 70.6% had diffuse large B-cell lymphoma (DLBCL) and the remaining had primary mediastinal large B-cell lymphoma (PMBCL). The rest were treated with Tisa-cel; 60.0% had DLBCL and the others had B-cell precursor acute lymphoblastic leukaemia (ALL). Median age in the ALL population was 9 years (6–14) and

mean age in patients with DLBCL and PMBCL was 57.7 years ($\pm$ 8.8). Median hospital stay was 15 days (13–21). Two patients died during admission and one remained admitted at the data cut-off date. 15.6% required admission to the ICU and mean stay was 7 days ($\pm$ 6.1). Two patients presented with mild hypersensitivity reaction during CAR-T cell infusion. 81.3% presented CRS and neurological toxicity occurred in 37.5%. During admission, 78.1% presented with febrile neutropenia and 15.6% had active infections. Hypogammaglobulinaemia was observed in three patients. Tocilizumab and corticosteroids were administered in 21.9% of patients in both cases. CRS and febrile neutropenia rates were similar in patients treated with Tisa-cel and Axi-cel (73.7% vs 88.2% and 80.0% vs 76.5%, respectively). Neurological toxicity was more frequent with Axi-cel (52.9% vs 20%).

Conclusion and relevance CAR-T cell therapy was generally well tolerated with a low rate of severe or life threatening AE. CRS was the most frequent AE and no differences were found between Axi-cel and Tisa-cel. Neurological toxicity rates were similar to those observed in clinical trials with Tisa-cel and lower than with Axi-cel. The need for tocilizumab and/or corticosteroids in Axi-cel patients was lower than in clinical trials.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-312 PHARMACEUTICAL INTERVENTIONS IN A NON-ONCOHAEMATOLOGICAL DAILY HOSPITAL

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Background and importance The role of the pharmacist in the validation and dispensing of medications is already known. But the increasingly frequent use of high cost drugs makes that role essential for the sustainability of health systems.

Aim and objectives To describe and analyse the pharmaceutical interventions carried out in a non-oncohaematological daily hospital (NOHDH) and to evaluate the economic impact of these interventions.

Material and methods From April 2019 to March 2020, pharmacist interventions in the validation and dispensing of electronic prescriptions of intravenous treatments in the NOHDH were recorded. It should be noted that preparation of infusions is not centralised in the pharmacy but is carried out in the daily hospital units. Infusions prepared in the pharmacy, acute treatments and intravenous iron were excluded. To calculate the economic impact, only the dose administered and the average cost of drugs during the year of the study were considered.

Results 30 interventions were carried out in 434 patients (6.9% patients) and 2240 dispensations (1.3% dispensations). 29 were accepted (97%). They were classified according to the type of intervention: 15 presentation changes (14 to a biosimilar), 10 dose adjustments (5 to commercial presentations), 4 request errors (1 of dose and 3 of administration date) and 1 change of medication. Intervention according to services: 10 rheumatology (9.6% of patients and 2.2% of dispensations), 5 nephrology (26.3% and 11.4%), 4 digestive

(2% and 0.4%), 4 neurology (11.1% and 1.3%), 3 nursing unit (0.7% and 0.13%), 1 haematology (7.7% and 1.9%), 1 allergy (4.3% and 0, 61%), 1 paediatrics (10% and 2%) and other (9.1% and 3.6%). Intervention according to drug: 10 rituximab (23.3% and 11.5%), 7 infliximab (3.6% and 0.74%), 5 immunoglobulins (9.8% and 1.1%), 4 tocilizumab (16.7% and 3.3%), 3 vedolizumab (5.6% and 1.1%) and 1 reslizumab (4.3% and 0.7%). The total estimated savings from performing the interventions was 12 186.9€ (406.2€ / intervention).

Conclusion and relevance Approximately half of the interventions carried out consisted of exchange to the biosimilar drug, after consensus. Although the number of interventions was low, their economic impact is important. Despite not being able to prepare these medications centrally and individually, the validation of the prescription and monitoring of the dispensations by the pharmacist is essential.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-313 EXPERIENCE OF THE USE OF BARICITINIB IN COVID-19 PNEUMONIA

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Background and importance Baricitinib is an immunosuppressive agent included as one of the therapeutic options for COVID-19 in the Spanish protocol Agencia Española del Medicamento y Productos Sanitarios.

Aim and objectives The objective was to assess the effectiveness of this drug in hospitalised but non-critically ill patients.

Material and methods An observational retrospective study was conducted in a third level hospital from 26 March to 5 May. Inclusion criteria were: hospitalised patients diagnosed with COVID-19 pneumonia and treated with baricitinib. Data collected were: age, gender, comorbidities, severe pneumonia diagnosis, ferritin and interleukin 6 (IL-6) prior to the beginning of treatment with baricitinib, standard of care according to the hospital's protocol, concomitant treatment with anakinra, duration of treatment with baricitinib, average hospital stay (AHS), deaths and hospital discharges. The data were collected from the electronic medical records and the hospital's management department.

Results 171 patients treated with baricitinib were included, with an average age of 69.5 (34–96) years. 71.3% (122) were men. 87.1% (149) had comorbidities and 73.1% (125) were diagnosed with a severe pneumonia, with 25% of them dying (31). Median duration of treatment with baricitinib was 5 days (1–12). AHS for the baricitinib group was 14.60 (3–47) days, and AHS for the whole sample of patients diagnosed with COVID-19 pneumonia was 17.2 days. 23.4% (40) of patients had high levels of ferritin (>2500 UI/L). Among them, 87.5% (35) were discharged and 12.5% (5) died. IL-6 levels were high (>40 U/L) in 29.8% (51) of patients, <40 U/L in 37.4% (64) and not measured in 32.7% (56). In the group with high IL-6 levels, 70.6% (36) were discharged and 29.4% (15) died. Among those with normal levels of IL-6, 93.8% (60) were discharged and 6.3% (4) died. 84.2% (144) of baricitinib

patients were also treated with the SoC. During the hospital stay, 31.0% (53) of patients were treated with anakinra and baricitinib, 83.0% (44) were discharged and 17.0% (9) died. Global mortality of the whole sample of patients diagnosed with COVID-19 pneumonia was 18.1% (31).

Conclusion and relevance AHS for baricitinib patients was shorter than for the whole sample of COVID-19 patients. The percentage of patients with high levels of IL-6 was superior to that of patients with high ferritin, with mortality greater in patients with IL-6 >40 UI/L. Hence IL-6 level appears to be a better prognostic factor of mortality than ferritin. This could also be related to a greater patient's immune response. Regarding treatment effectiveness, mortality of patients who were treated with SoC plus baricitinib was similar to that of patients treated with anakinra plus baricitinib.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-314 3 DAY COURSE OF LOW DOSE SUBCUTANEOUS ANAKINRA IN PATIENTS WITH REFRACTORY MODERATE-SEVERE COVID-19: A PROOF-OF-CONCEPT STUDY

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Background and importance Many patients with moderate-severe COVID-19 develop immune dysregulation characterised by marked activation of innate immunity, elevation of acute phase reactants and release of proinflammatory cytokines (eg, interleukin 1 (IL-1) and IL-6), thus creating a hyperinflammatory state.

Aim and objectives To determine the feasibility and safety of fighting hyperinflammation in patients with refractory moderate-severe COVID-19 by using a 3 day course of low dose subcutaneous anakinra.

Material and methods A prospective study was conducted in two hospitals in Spain, from 1 April to 8 May 2020, of nine hospitalised patients refractory to standard-of-care treatment with laboratory confirmed SARS-CoV-2 infection, a clinical course of at least 5 days, radiological pneumonia and moderate-severe COVID-19 according to clinical/analytical criteria. Patients received a daily subcutaneous dose of anakinra 100 mg for 3 consecutive days. The primary outcome was radiological improvement 72 hours after the first administration, together with appropriate clinical and analytical changes according to a combined set of response criteria. Secondary outcomes included incidence of serious adverse events, mortality, need for invasive ventilation at days 3 and 14, and days of hospitalisation.

Results All patients (aged 48–88 years) had bilateral pneumonia and received hydroxychloroquine; 7 received azithromycin, 5 ceftriaxone, 3 cyclosporine, 2 lopinavir/ritonavir, 1 interferon and 6 corticosteroids. Anakinra was introduced between 1 and 17 days (median 8 days) after admission. Six patients reached the primary outcome at day 3. An improvement in